

ATTACHMENT

AMERICAN ARBITRATION ASSOCIATION

IN THE MATTER OF THE
ARBITRATION BETWEEN

MONSANTO COMPANY,

Claimant,

and

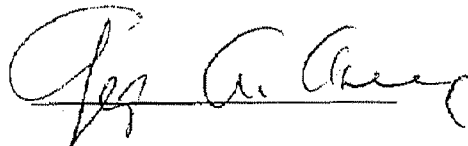
RITTER CHEMICAL, LLC,

Respondent.

FIFRA Case No. 16 171 Y 00450 10

PUBLIC AWARD ORDER

Pursuant to Section IV of the Panel's Award dated June 20, 2013, and the Panel's Protective Order, dated October 28, 2011, in the above-referenced arbitration proceeding, the parties have conferred and agreed upon the redactions set forth in the attached version of the Panel's Award. Accordingly, the attached redacted version of the Panel's Award is available for immediate public release.



For The Panel

AMERICAN ARBITRATION ASSOCIATION

Commercial Arbitration Tribunal

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MONSANTO COMPANY,*
("Claimant", "Monsanto")*
and* FIFRA Case No.:
RITTER CHEMICAL, LLC,* 16 171 Y 00450 10
("Respondent", "Ritter")*
_____*

AWARD

I. INTRODUCTION

Claimant, Monsanto Company (“Monsanto” or “Claimant”), initiated these proceedings against Respondent, Ritter Chemical, LLC (“Ritter” or “Respondent”) pursuant to The Federal Insecticide, Fungicide, and Rodenticide Act, 7 U.S.C. 136-136y (“FIFRA”) and the FIFRA Arbitration Rules, 29 C.F.R. Part 1440-Appendix (“FIFRA Rules”). Monsanto is seeking to recover \$7,688,000.00 from Ritter as data compensation in connection with Ritter securing from the U.S. Environmental Protection Agency (“EPA”) its registrations for the herbicide, glyphosate. Claimant Monsanto Company’s Post-Hearing Brief, dated February 27, 2013 (“Monsanto Brief”) at 100. Although Ritter agrees that it owes some compensation to Monsanto, it maintains that this amount is \$59,779.00. Ritter’s Post Hearing Brief, dated February 27, 2013 (“Ritter Brief”) at 97.

The record of this case is voluminous. The Panel heard testimony from the parties’ fact and expert witnesses in two hearing sessions which totaled fourteen (14) days. Hundreds of exhibits were admitted into evidence.

Based upon our full and careful consideration of this record and the arguments and authorities presented, and for the reasons described herein, we award to Claimant the amount of One Million Eight Hundred Twenty-One Thousand Two Hundred Thirty-Nine Dollars (\$1,821,239.00).

II. PROCEDURAL BACKGROUND

In accordance with FIFRA and the FIFRA Rules, Claimant instituted this proceeding pursuant to its Demand for Arbitration, dated June 3, 2010. Pursuant to the agreed case management order for the proceeding, Claimant filed its Statement of Claim (“SOC”) and Respondent filed its Statement of Position. The Panel entered an agreed Protective Order to govern the proceeding.

Following a period of discovery, Respondent filed a motion to strike (the “Motion to Strike”) certain categories of data in Monsanto’s SOC. Specifically, Ritter sought to strike Monsanto’s “label

development data” as listed on Exhibit 4 to the SOC (the “Exhibit 4 Data”), Monsanto’s “Roundup Ready registration-related data” as listed on Exhibit 3 to the SOC (the “Exhibit 3 Data”) and certain of Monsanto’s data which were listed on Exhibit 2 to the SOC (the “Exhibit 2 Data”) concerning the “AMPA” glyphosate metabolite (the “AMPA Data”). After Monsanto filed its opposition to the Motion to Strike, and Ritter filed its reply, the Panel heard in-person argument. The briefing, declarations and other evidence and materials presented by the parties were extensive. Although not subject to the Federal Rules of Civil Procedure in this FIFRA arbitration, the Panel deemed it appropriate to treat the Motion to Strike as in the nature of a motion for partial summary judgment and applied traditional summary judgment review and burden of proof standards in its consideration of the Motion to Strike. In its ruling, dated April 9, 2012, we found that there were many material facts in dispute and that those disputes should be resolved on the basis of a full evidentiary record developed in a hearing at which the parties’ expert and fact witnesses could be questioned and cross-examined and their credibility evaluated. Accordingly, the Panel denied the Motion To Strike.

Although the evidentiary hearing was originally scheduled to begin on February 20, 2012, that date was continued to June 5, 2012 in response to a request from Respondent based on the unavailability of [REDACTED] to participate in the hearing [REDACTED]. As a result of the withdrawal of Ritter’s attorneys, DLA Piper, in late April 2012, to which Monsanto did not object, Ritter requested a further continuance of the hearing date to locate and engage new counsel. In our ruling of May 11, 2012, we granted that request for good cause shown (FIFRA Rules, Rule 21(b)) and directed that the hearing begin on October 8, 2012. During a pre-hearing telephonic status conference with the parties on August 29, 2012, the Panel learned from Ritter that it likely would not be represented by counsel at the hearing and would instead proceed *pro se*. Monsanto made its required FIFRA Rule 23(d) disclosures to Ritter on September 17, 2012 as was previously agreed to by the parties. Although required also to make its Rule 23(d) disclosures on that date, Ritter did not do so. Instead, its

new counsel, the Immix Law Group, entered its appearance. Ritter then requested that the hearing date be further continued to afford counsel ample opportunity to become familiar with the case, to complete its FIFRA Rule 23(d) disclosures and to prepare for the hearing. The parties then agreed on, and the Panel approved, a further revised schedule whereby there would be two hearing sessions, one to begin in mid-October of 2012 and a second to begin in December of 2012, after Ritter made its FIFRA Rule 23(d) disclosures. It was agreed that Ritter would not present its evidence until the December hearing session.

The initial hearing session commenced on October 15, 2012 and continued on October 16, 22, 23, 24, 25 and 26, 2012. The second hearing session commenced on December 13, 2012 and continued on December 14, 17, 18, 19, 20 and 21, 2012. In support of its claims, Monsanto presented extensive testimony from a number of fact witnesses and from several regulatory and accounting expert witnesses. Ritter's counsel conducted extensive and vigorous cross-examination of Monsanto's fact and expert witnesses. Although Ritter had designated fact witnesses to testify, including

it informed the Panel during the second session that it had decided not to present those witnesses and to proceed instead only with its expert witnesses. In addition to relying on many of Monsanto's exhibits, Ritter also introduced a number of its own exhibits at the hearing. At the conclusion of the hearing, in response to a question from the Panel Chairman, both parties stated that they had no further proofs to offer or witnesses to be heard in the case.

An agreed schedule for submission of post-hearing briefing, to include initial and reply briefs, was established at the end of the hearings. The initial briefs (up to 100 pages) included an opportunity for the parties to address a number of written, specific questions which the Panel posed to the parties after the hearings. It was also agreed at the end of the hearings that the Panel would decide, after considering the briefs, whether final oral arguments would be helpful. The Panel concluded that final

arguments were not needed and the hearings were closed on April 22, 2013. At the Panel's request, the parties agreed that the Award would be issued by June 21, 2013.

III. FINDINGS OF FACT AND CONCLUSIONS

A. The Parties

Monsanto is a large international agricultural chemical and biotechnology company. Based in St. Louis, Missouri, Monsanto has long been a pioneer in the development of innovative and technologically advanced approaches to improving agricultural production. Its extraordinarily successful herbicide, glyphosate, has been sold and marketed under the brand name, "Roundup." It has been the most widely used herbicide in the history of U.S. agriculture and has also been widely used elsewhere. Monsanto expended substantial effort and expense over a period of years to generate the required data necessary to support approval of glyphosate by the U.S. Government, acting through the Environmental Protection Agency ("EPA"). Glyphosate was first registered for use in the U.S. in 1974. Patent protection for glyphosate expired in 2000.

As discussed below, Monsanto also developed genetically engineered seeds for a number of agricultural crops which were resistant to glyphosate when applied to the growing crops ("glyphosate-tolerant" or "Roundup Ready" crops). The development of those seeds and the revolutionary new uses of glyphosate on those crops were also the subject of substantial effort and expense by Monsanto in order to obtain and maintain U.S. Government approval of those uses. The appropriate treatment of those efforts and expenses for FIFRA data compensation purposes is central to this proceeding.

Ritter has facilities in Oregon and Texas. It provides chemical products and services to assist growers and dealers. Among its other operations, Ritter produces and sells glyphosate. Ritter, however, was not involved in the development of glyphosate or in securing and maintaining government approvals for glyphosate including for the new uses on glyphosate-tolerant crops.

B. Glyphosate and the Parties' Relevant Glyphosate Registrations

1. Glyphosate

Monsanto secured a federal registration for glyphosate in 1974. Since it is non-selective, glyphosate generally kills all green plants. Although widely successful, this severely limited its agricultural use since it would kill not only weeds, but also growing crops, when applied. As a result, with limited exceptions, glyphosate use with agricultural crops was limited to pre-emergence application, i.e., before planting crop seed; at the time of planting; or, before the crop emerged from the soil.

In the early 1990's, Monsanto expended substantial research and development cost and effort as it used the tools of modern agricultural biotechnology to successfully develop genetically engineered or biotechnology-derived crops that were glyphosate-tolerant. As a result, for the first time, glyphosate could be sprayed directly on these crops without harming the crops while destroying the surrounding weeds. The kind of revolutionary gene-specific manipulation which Monsanto accomplished created glyphosate-tolerant crops. This was a result that had never before been accomplished in commercial plant breeding.

Not surprisingly, glyphosate-tolerant crops have become extraordinarily popular with growers. At the same time, the glyphosate market has "exploded" as a result of these new agricultural uses for glyphosate on glyphosate-tolerant crops. Between 1992 and 2002, glyphosate use in the United States increased six-fold to 102 million pounds. This increase was largely attributable to the rapid adoption by growers of Monsanto's glyphosate-tolerant crops. By 2001, according to EPA, glyphosate had become the most widely used agricultural pesticide (an herbicide is a type of pesticide) in the United States.

The ability to use glyphosate directly on glyphosate-tolerant crops has resulted in significant additional agricultural and environmental benefits. It has allowed growers to move away from older, and in some cases, more toxic pre-emergence herbicides that also may have a greater likelihood of

contaminating groundwater or surface water. Importantly, and as discussed in greater detail herein, the development of glyphosate-tolerant crops has played a significant role in allowing growers to adopt reduced “tillage” or “no-till” options in their farming practices. This, in turn, has had a significant role in reducing soil and chemical run-off into surface water, as well as reducing atmospheric emissions from agricultural equipment because tractors and other equipment are not used in the fields as much. All of this has contributed to important reductions in the environmental impact of production agriculture. The ability of growers to use glyphosate with glyphosate-tolerant crops also provides them with distinct, measurable, and economically significant advantages over the use of other kinds of herbicides.

Besides its use in agriculture, glyphosate is also widely used, and is highly effective, in controlling weeds in lawns and gardens, nurseries, greenhouses, rights-of-way and in other ways. It is registered in the United States for more uses than any other herbicide. It is practically nontoxic by ingestion. Its toxicity from dermal or inhalation exposure is also quite low. Glyphosate has not been shown in testing to have any reproductive, mutagenic or teratogenic effects. Testing also has established that it is not carcinogenic. When glyphosate comes into contact with the soil, it rapidly binds to soil particles and is inactivated. Unbound glyphosate is degraded by bacteria. Because of its adsorption to soil, glyphosate is not easily leached and is rarely found as a contaminate in groundwater.

2. Monsanto’s New Use Registrations for Glyphosate-Tolerant Crops

Monsanto has secured approvals from EPA for the use of glyphosate on a number of glyphosate-tolerant crops, as follows:

Soybeans: On May 27, 2004, Monsanto submitted an application to EPA to use glyphosate on its first glyphosate-tolerant crop, Roundup Ready Soybean 40-3-2. On May 24, 1995, EPA issued a conditional registration (discussed in greater detail herein) for this new use of glyphosate on glyphosate-tolerant soybeans and this soybean crop product was added to Monsanto’s glyphosate label. On

October 23, 2008, another soybean product, Roundup Ready 2 Yield Soybean MON 89788, was added to Monsanto's glyphosate label after EPA approval.

Cotton: On March 6, 1994, Monsanto submitted an application to EPA to use glyphosate on another glyphosate-tolerant crop, Roundup Ready Cotton 1445. On February 21, 1996, EPA issued a conditional registration (discussed in greater detail herein) for this new use of glyphosate on glyphosate-tolerant cotton and this cotton crop product was added to Monsanto's glyphosate label. Roundup Ready Flex Cotton 88913, another cotton crop product, was added to Monsanto's glyphosate label following EPA approval of this new use on February 9, 2005.

Corn: On June 29, 1995, Monsanto submitted an application to EPA to use glyphosate on another glyphosate-tolerant crop, Roundup Ready Corn GA 21. On March 28, 1997, EPA issued a conditional registration (discussed in greater detail herein) for this new use of glyphosate on glyphosate-tolerant corn and this corn crop product was added to Monsanto's glyphosate label. On December 18, 2002, Monsanto requested approval from EPA to add another glyphosate-tolerant corn product, Roundup Ready 2 Corn NK603, to its label. EPA granted its approval on June 23, 2003. On January 9, 2006, Monsanto requested approval from EPA to add an additional glyphosate-tolerant corn product, Roundup Ready 2 Corn MON 88017, to its label. EPA granted its approval on May 18, 2006.

Canola: On April 3, 1998 Monsanto submitted an application to EPA to use glyphosate on another glyphosate-tolerant crop, Roundup Ready Canola RT73. On March 31, 1999, EPA issued a conditional registration (discussed in greater detail herein) for this new use of glyphosate on glyphosate-tolerant canola and this product was added to Monsanto's glyphosate label.

Alfalfa: On March 28, 2002, Monsanto submitted an application to EPA to use glyphosate on another glyphosate-tolerant crop, Roundup Ready Alfalfa. On June 15, 2005, EPA approved the addition of this new use of glyphosate and this product was added to Monsanto's glyphosate label.

3. Ritter's Glyphosate Registrations

Ritter has a technical, a manufacturing, and an end-use glyphosate registration. It first applied for its technical registration on November 9, 2004, and the registration was issued on February 9, 2005. Ritter first applied for its manufacturing use registration on October 12, 2004, and the registration was issued on June 7, 2005. Ritter first applied for its end-use registration on October 4, 2004 and secured that registration on June 20, 2005.

Ritter applied to amend its technical and manufacturing use registrations on February 22, 2011, and those amendments were approved on March 21, 2011. It applied to amend its end-use registration on October 7, 2010, and the amendment was approved on December 6, 2010. As discussed more fully below, Ritter used and relied on the so-called "cite-all" method to support all of its applications and amendments and secured its registrations on that basis. In selling and marketing its glyphosate products, Ritter employs labels which contain both conventional uses for glyphosate and glyphosate-tolerant uses. Its labels include uses on all of the glyphosate-tolerant crops (discussed above) as to which Monsanto applied for and has secured EPA approval.

C. Statutory and Regulatory Background

1. FIFRA Section 3(c)(1)(F)

In this section of the Award, we highlight certain provisions of FIFRA as background for our consideration of Monsanto's claims. Those claims in this proceeding arise under Section 3(c)(1)(F) of FIFRA. This section is one of several provisions of FIFRA that authorize the use of test data generated by one company to support federal pesticide registration held or sought to be held by another company. Section 3(a) of FIFRA requires the registration with EPA of all pesticide products sold or distributed in the United States. In order to obtain the original registration of a pesticide, an applicant must submit certain test data as specified under guidelines published by EPA. FIFRA Sections 3(c)(1)(F) and 3(c)(2)(A).

EPA also can require additional data to be provided to support or maintain an existing registration. It also can condition its initial approval of a registration on the provision of further required data. These important subjects are discussed in greater detail herein.

FIFRA affords a registrant of an active ingredient, if it secured its registration after September 30, 1978, with the exclusive right to use, e.g., to distribute and sell, the pesticide for a period of ten years. During that period, another applicant seeking to register a pesticide product containing the same active ingredient (i.e., a “generic” pesticide) may use the data submitted by the original data submitter only if it secures written permission from the original submitter/registrant. Section 3(c)(1)(F)(j).

Since glyphosate was originally registered in 1974, Monsanto’s data which were submitted in support of that registration were not eligible for FIFRA’s 10-year exclusive-use protection. Once test data concerning a pesticide have been submitted to EPA and any exclusive use period for the data has expired, applicants for registration of generic pesticides may rely on the data to support applications to EPA without the permission of the data submitter. Id.; Section 3(c)(1)(F)(iii). However, in order to rely on data which was previously submitted by another party, a so-called “follow-on” applicant such as Ritter must make an offer to compensate the original submitter. The compensation amount is established either by agreement of the parties or through an award in an arbitration proceeding such as the instant case. As previously mentioned, there are specific rules, the FIFRA Rules, which govern FIFRA arbitration proceedings.

Issuance of a follow-on applicant’s registration, and that applicant’s subsequent entry into the market, is not dependent upon the resolution of its data compensation obligations. Id. (“Registration action by the [EPA] Administrator shall not be delayed pending the fixing of compensation.”)

Section 3(c)(1)(F) only grants follow-on registrants the right to cite and rely on another company’s data to support federal registrations. They do not receive the right to own or to possess an actual “hard” copy of the test data. They also do not receive the right to use the data to support

international pesticide registrations or the right to use the data to support U.S. state registrations in those states that, like many foreign jurisdictions, require follow-on applicants to obtain a “letter of authorization” to rely on previously submitted data. Follow-on registrants do not receive the right to share in any future compensation paid to the original data submitter by new generic applicants.

The data sharing provisions of FIFRA serve several important purposes. In Ruckelshaus v. Monsanto Co., 467 U.S. 986 (1984), the U.S. Supreme Court noted that the “the public purpose behind [FIFRA’s] data-compensation provisions is clear from the legislative history, [i.e., to] eliminate costly duplication of research and streamline the registration process . . . thereby allowing greater competition among producers of end-use products.” Similarly, in Thomas v. Union Carbide Agric. Prods. Co., 473 U.S. 568 (1985), the Court noted that the purpose of the data sharing program is “to streamline pesticide registration procedures, increase competition, and avoid unnecessary duplication of data-generation costs.” The Court indicated that “Congress viewed data-sharing as essential to the registration scheme...[it] serves a public purpose as an integral part of a program safeguarding the public health.” Id. at 573, 589.

Consistent with these goals, the Court also indicated that compensation under FIFRA is defined as an equitable sharing of the costs to generate data required by EPA. Thus, the Court in Union Carbide, supra, tracking relevant developments in FIFRA’s legislative history, observed that FIFRA provides the “statutory authority for the use of previously submitted data as well as a scheme for sharing the costs of data generation.” 473 U.S. at 572. As the Court further explained:

The 1978 amendments represent a pragmatic solution to the difficult problem of spreading the costs of generating adequate information regarding the safety, health and environmental impact of a potentially dangerous product. Congress...could have authorized EPA to charge follow-on registrants fees to cover the costs of data and could have directly subsidized FIFRA data submitters for their contributions of needed data. . . . Instead, it selected a framework that collapses the two steps into one, and permits the parties to fix the amount of compensation, with binding arbitration to resolve intractable disputes. 473 U.S. at 590.

The legislative history of FIFRA, and judicial pronouncements, however, also confirm that Congress intended the cost sharing provisions of FIFRA to protect an innovator such as Monsanto in recovering its allowable costs in developing necessary, novel data to support EPA approval of a pesticide or, as here, to support what can only be described as revolutionary new uses for that pesticide. According to one federal court: "The primary purpose of the data-sharing provision [of FIFRA] is to guarantee compensation to original data submitters for the compelled use of their data." Cheminova A/S v. Griffin, L.L.C., 182 F. Supp. 2d 68, 74 (D.D.C. 2002). Clearly, a fundamental purpose of the data-sharing provision of FIFRA is to encourage efficiency and non-duplication of data generation. However, this should not be accomplished in such a way that a developer and innovator such as Monsanto is disincentivized to undertake the required research. It also should not be accomplished in such a way that a follow-on registrant does not pay an equitable share of the costs of the data which EPA required.

In this proceeding, as discussed in greater detail herein, Ritter has in many instances taken a view we do not accept as to the kind of costs properly to be considered as allowable "compensation" to be paid under FIFRA Section 3(c)(1)(F)(iii). This is supported by a brief review of the relevant legislative history of this critical provision.

As discussed by the Supreme Court in Ruckelshaus, the comprehensive 1972 amendments to FIFRA changed the statute from what was essentially a labeling law into a regulatory one with mandatory licensing. Congress added the registration requirement that EPA determine that a pesticide will not cause "unreasonable effects on the environment." Id. at Section 3(c)(5)(C) and (D). Congress also added a provision whereby EPA could consider data submitted by one applicant in support of another application pertaining to a similar product so long as the follow-on applicant offered to compensate the original submitter. See Ruckelshaus v. Monsanto at 991.

As originally passed by the House of Representatives, the bill which preceded the 1972 amendments did not mention compensation at all. Rather, the bill only required that the subsequent

applicant secure the permission of the original data submitter. This allowed a data submitter to block reliance by another on its data. According to Representative Thomas Foley, this would reward “research investment in order to stimulate and encourage such investment.” H.R. Rep. No. 92-511 at 20, 69 (1971). There was considerable debate in Congressional committees as to whether the data permission reliance proposal should be deleted because the proposal did not go far enough to protect the original data submitter. The Senate Committee on Agriculture and Forestry was amenable to giving a data submitter exclusive rights to the data. The Senate Commerce Committee, however, disagreed; it felt that requiring duplicate test data could stifle incentives to develop new pesticides. That Committee proposed an amendment to strike the language. S. Rep. No. 92-938, pt. 2, at 12 (1972). The Committee on Agriculture and Forestry expressed concern over the proposed amendment in a supplemental report:

The purpose of the provisions proposed to be deleted is to give manufacturers an incentive to undertake the research necessary to develop better and safer pesticides. The costs of testing a product to determine the pests for which it is effective, the commodities on which is [sic] can safely be used, and the proper method of application may be very great. If the project is not patentable or if the patent protection has expired, there is nothing to prevent a competitor from registering a similar product. Under such circumstances, the first applicant has no opportunity to recover his research costs and little incentive for undertaking that research. The provision proposed to be stricken by the Commerce Committee amendment is designed to provide the necessary incentive for the production of safer and better pesticides to protect the environment. . . . *Id.* at 2-3, 12.

Ultimately, a compromise resulted: the exclusive use of data provision remained but a mandatory licensing system was established under which “permission to use test data in return for a reasonable share of the cost of producing the data would be required.” *Id.* at 69 (Explanation of Compromise Amendment in the Nature of a Substitute). Congress’s intent behind the “reasonable share of the cost” requirement was expressly stated:

Legislative intent with respect to section 3(c)(1)(D). . . . “[I]t is recognized that in certain circumstances it might be unfair or inequitable for government regulation to require a substantial testing expense to be borne by the first applicant, with subsequent applicants thereby gaining a free ride. On the other

hand, unnecessary duplicative testing would represent a wasteful, time-consuming, and costly process resulting in a substantial misallocation of resources. Thus it was decided that fairness and equity require a sharing of the governmentally required cost of producing the test data used in support of an application by an applicant other than the originator of such data.” *Id.* at 72-73.

The “reasonable share of the cost of producing the test data” requirement language was then revised in conference committee to “reasonable compensation for producing the test data.” H.R. Rep. No. 92-1540, at 9 (1972) (Conf. Rep.) This language was included in the 1972 amendments, as adopted, along with the further requirement that EPA make a determination as to that compensation amount, subject to judicial review by a federal district court but without delaying use of the data by the follow-on applicant.

In 1975, Congress further amended Section 3(c)(1)(D) to provide that its data-consideration provisions would only apply to data submitted on or after January 1, 1970. Congress, once again, took this opportunity to further underscore what it intended when it established the mandatory compensation scheme in the 1972 amendments: “. . . It was apparent that new data requirements would be imposed by the [EPA] Administrator, and that satisfaction of these data requirements would involve considerable expense. The provision reflects the sound conclusion that all persons who wish to profit from the fruits of this expense should have to bear a fair share of the financial burden.” S. Rep. No 94-452, at 10 (1975), *reprinted* in 1975 U.S.C.C.A.N. 1359, 1367.

FIFRA was further amended in 1978. According to the Supreme Court, these amendments resulted in part from a litigation logjam tied to data compensation disputes. Thomas v. Union Carbide, *supra*, at 573. According to Senator Leahy, although Congress continued to view data-sharing as essential to the registration process, data valuation disputes had tied up the registration process and EPA “lacked the expertise necessary to establish the proper amount of compensation” and had to be relieved of the data valuation responsibility. 123 Con. Rec. 25,709 (1977). As mentioned above, among the revisions to FIFRA, the 1978 amendments granted data submitters a 10-year period of exclusive use

for data submitted after September 30, 1978, during which the data could not be cited without the original submitter's permission. (As indicated above, the exclusive use provisions do not apply to this case.) These amendments also replaced having the EPA determine the amount of compensation by a system of binding arbitration.

The 1978 amendments also further revised the data compensation obligation for the follow-on from "offer[ing] to pay reasonable compensation for producing the test data" to be relied upon to "offer[ing] to compensate the original data submitter." FIFRA Section 3(c)(1)(F)(iii), 7 U.S.C. 136a(c)(1)(F)(iii). We have concluded that this evolution of the salient language concerning the follow-on's data compensation obligation indicates that Congress intended to expand a follow-on applicant's obligation to the original data submitter. We have noted that Arbitrator Charnoff shares that view. See I. Pi. Ci and Albaugh, Inc., No. 16 171 00216 95, Order Denying Motion to Dismiss Royalty Claim as a Matter of Law (July 11, 1996). The legislative history of the 1978 amendments also suggests that Congress recognized that FIFRA's data compensation provisions should not serve to disincentivize new pesticide product and new use development.

There are no definitions of "compensation" or "compensable data" in FIFRA or in the implementing regulations. Accordingly, in cases such as this one where the parties have been unable to agree on the amount of compensation and, indeed, are "miles apart" as to what that amount should be, this amount is to be determined in this arbitration proceeding based upon the entire evidentiary record and our consideration of the applicable law.¹

¹ Ritter asserts that there is a six-part "test for compensability" which requires that the information for which compensation is claimed (1) is data, test, or test results; (2) is in EPA's files; (3) is required for registration as of the date EPA approved the applicant's application; (4) concerns a registered product that is identical or substantially similar to the applicant's product's composition and uses; (5) is reviewed, considered and relied upon by EPA for registration; and (6) is not excluded from compensation. According to Ritter, every element of this test must be proven for each item as to which compensation is claimed. Ritter Reply Brief, dated April 5, 2013 ("Ritter Reply Brief") at 8. Although Ritter in its "test" has identified subjects to be considered, as appropriate, in FIFRA cases in assessing the compensability of particular data, there is no "test for compensability" in FIFRA or in the regulations.

2. EPA Regulations Implementing FIFRA Section 3(c)(1)(F)

FIFRA requires all new pesticides and new uses of pesticides to be registered with EPA. FIFRA Section 3(a), 7 U.S.C. 136(a). EPA requires data from an applicant in order to grant the registration. FIFRA Section 3(c), 7 U.S.C. 136(c). An applicant, at its own cost, can generate its own data and rely on that data for purposes of its application. See 40 C.F.R. 158.1(a), 152.50, 152.92, 152.93. Alternatively, an applicant can choose to rely on another party's data to support its application. See FIFRA 3(c)(1)(F)(iii), 7 U.S.C. 136(c)(1)(F)(iii).

In 1984, EPA promulgated regulations, currently codified at 40 C.F.R. Part 152, Subpart E, implementing the data-sharing provisions of FIFRA Section 3(c)(1)(F). 30 Fed. Reg. 30884 (Aug. 1, 1984). In promulgating these regulations, EPA pointed out that FIFRA Section 3 is "primarily concerned with protecting the economic interests of data submitters" and "limits the extent to which an applicant may reference another person's data to satisfy the Agency's data requirements." 49 Fed. Reg. 30,884, 30,888 (Aug. 1, 1984).

Under EPA's regulations, applicants wishing to rely on previously submitted data may choose one of two methods of data support – the "selective" method or the "cite-all" method.

Under the "selective" method, the applicant lists in its application EPA's Part 158 data (or "guideline") requirements which are applicable to its product. These regulations found at 40 C.F.R. 158.30 describe in general terms the types of studies to be submitted, including those which relate to product chemistry, product performance, toxicology – humans and domestic animals, hazards to non-

We also are unaware of any case in which an arbitrator or court has espoused such a test. We believe that compensability of particular data in a "cite-all" method case like the one before us should be considered in light of the criteria established by EPA in Section 152.86(d) of the regulations, discussed herein. We also believe that in determining whether Monsanto has met its burden to prove compensability of particular data, it is incumbent upon us to consider the entirety of the evidentiary record as presented to us and to draw reasonable inferences from the established facts.

target organisms, applicator and post-application exposure, spray drift, environmental fate and residue chemistry.

The “selective” method applicant then cites, and offers to pay for, particular studies specifically identified in its application for EPA’s consideration to satisfy these guidelines. 40 C.F.R. 152.90(a) and (b)(3), 152.93(b)(2)(iii). Each of these studies bears an 8-digit Master Record Identification Number (“MRID”) which EPA assigned to the study when originally accepted by the agency. The follow-on applicant is required to identify by MRIDs the particular studies being relied upon. 40 C.F.R. 152.93(b)(2)(ii) (requiring the applicant to identify each cited study “by title, EPA Accession Number or Master Record Identification Number . . .”) See also EPA Form 8570-35 (data matrix form, 3rd column, entitled “MRID number”). EPA maintains a computerized database, operated by Purdue University, that contains information on all Part 158 guideline studies submitted to EPA together with their MRIDs.

Through use of the “selective” method, however, the applicant seeks to narrow its potential data compensation liabilities by specifically selecting the data requirements which it considers to be pertinent to its application and then citing, on a “data matrix”, the specific data that it believes satisfies those requirements. The possibility of having to pay compensation for several similar studies which may satisfy the same data requirement can be reduced since the applicant can generally demonstrate compliance by citing one valid study for each data requirement. 49 Fed. Reg. at 30,894. The applicant submits an offer to pay to each of the original data submitters whose data it has specifically relied upon in its application. As indicated, the applicant may also rely on its own data to satisfy application requirements. Use of the “selective” method can serve to significantly reduce a follow-on applicant’s overall data compensation liability.

When an applicant uses the “selective” method, EPA reviews the application to confirm that the appropriate data have been relied upon. According to EPA: “[T]he Agency expects that a decision to use the selective method will involve heavier paperwork burdens on the applicant, and will require the

Agency to devote more resources to reviewing the application to determine that the submitted materials comply with [FIFRA], with a concomitant increase in time and cost of registration review in general.” 49 Fed. Reg. at 30,894.

The regulations also include procedures whereby an original data submitter may challenge whether the follow-on applicant has sufficiently cited the original data submitter’s data.

Under the second method of data support, the “cite-all” method, the applicant cites to and relies upon “all data in Agency files that are pertinent to [EPA’s] consideration of the requested registration under FIFRA section 3(c)(5) . . . 40 C.F.R. 152.86. “Pertinent” data are defined as:

1. All data submitted with or specifically cited in the application; and
2. Each other item of data in the Agency’s files which: (i) Concerns the properties or effects of the applicant’s product, of any product which is identical or substantially similar to the applicant’s product, or of one or more of the active ingredients in the applicant’s product; and (ii) is one of the types of data that EPA would require to be submitted if the application sought the initial registration under FIFRA section 3(c)(5) of a product with composition and intended uses identical or substantially similar to the applicant’s product, under the data requirements in effect on the date EPA approves the applicant’s present application.
40 C.F.R. 152.86(d).

The applicant using the “cite-all” method is required to submit a “general offer to pay” to EPA whereby the applicant agrees to pay compensation “to other persons, with regard to the approval of this application, to the extent required by FIFRA.” 40 C.F.R. 152.86(c), 152.95(a). An applicant submits a general offer to pay by checking a box in Section II on EPA Form 8570-34, called “Certification with Respect to Citation of Data” (the “Certification”).

Section I of the Certification requires the applicant to identify its method of data citation. Section III of the Certification requires the applicant to make the acknowledgement required by 40 C.F.R. 152.86(d), under penalty of fine or imprisonment, that:

If the cite-all option or cite-all option under the selective method is indicated in Section I, this application is supported by all data in the Agency's files that (1) concern the properties or effects of this product or an identical or substantially similar product, or one or more of the ingredients in this product; and (2) is a type of data that would be required to be submitted under the data requirements in effect on the date of approval of this application if the application sought the initial registration of a product of identical or similar composition and uses. Ex. 303 at MONO87341.

In this proceeding, as indicated, Ritter used the "cite-all" method of data reliance to secure its glyphosate registrations and submitted general offers to pay as part of its glyphosate applications. In this way, Ritter was able, at minimal cost and quickly (e.g., in about 3 months for its initial glyphosate registration), to secure EPA approval. Use of this method for a follow-on applicant is simple, does not require the time and expense to generate data required by EPA, and is efficient. According to EPA:

In order to file an application under the cite-all method, an applicant is not required to determine which data requirements actually apply to his product. By securing the right to cite all relevant data in EPA's file, the applicant obviates the need for identifying specific data requirements, specific studies, or data submitters for specific studies. 49 Fed. Reg. at 30,893.

EPA has indicated that the nature and scope of its review of "cite-all" applications is quite different from its review of "selective" applications: [Applications under the cite-all method will be examined primarily to determine that the applicant's certification and general offer to pay have been correctly submitted. . . . This review will not be time-consuming, and the Agency will be able to resolve any problems quickly and directly with the applicant." 49 Fed. Reg. at 30,898.

However, use of the "cite-all" method can also be inherently risky for a follow-on applicant relative to its potential data compensation exposure. EPA has pointed this out on more than one occasion: "[T]he primary disadvantage of the cite-all method to the applicant is that he may be compelled to pay for the [sic] more than the minimum set of data required by Part 158." 49 Fed. Reg. at 30,893. "The cite-all method, while easier to use and less burdensome procedurally, potentially subjects

the applicant to an unknown or uncertain compensation liability.” 75 Fed. Reg. 68,297, 68,300 (Nov. 5, 2010).

The regulations also allow an applicant to use the “selective” method but to rely on the “cite-all” option to satisfy particular data requirements. 40 C.F.R. 152.95; 49 Fed. Reg. at 30,896 (discussing 40 C.F.R. 152.95) Under this method, known as the “selective cite-all” or cite-all option under the selective method, as with the “cite-all” method described above, the applicant is required to submit a general offer to pay with Certification to EPA.

In view of the obvious importance of EPA’s pesticide registration responsibility, it is not surprising that the application process can at times be a flexible one whereby the Agency may, or may not, require data and information to be provided to it. In this regard, 40 C.F.R. 158.30, entitled “Flexibility”, states:

- (a) FIFRA provides EPA flexibility to require, or not to require, data and information for the purposes of making regulatory judgments for pesticide products. EPA has the authority to establish or modify data needs for individual pesticide chemicals. The actual data required may be modified on an individual basis to fully characterize the use and properties, characteristics, or effects of specific pesticide products under review. The Agency encourages each applicant to consult with EPA to discuss the data requirements particular to its product prior to and during the registration process. 40 C.F.R. 158.30(a).

The ability of EPA to require the submission of data, specifically in addition to the “traditional” Part 158 guideline data, also is not surprising. In this regard, 40 C.F.R. 158.30(b) cautions applicants that “EPA may require the submission of additional data or information beyond that specified in this part if such data or information are needed to appropriately evaluate a pesticide product.” See also 40 C.F.R. 158.75.

Of particular relevance to this case is the ability of EPA to impose additional requirements by imposing conditions on registration. See 40 C.F.R. 152.115(c). (“The Agency may establish, on a case-

by-case basis, other conditions applicable to registrations to be issued under FIFRA sec. 3(c)(7).”) If the conditions are not satisfied, or if the Agency determines that no action has been taken to fulfill the conditions, then the registration may be canceled. See 40 C.F.R. 152.115(d).

D. Monsanto’s Claims

1. Claim Summary

As the Claimant in this proceeding, Monsanto has the burden of proof to demonstrate, by a preponderance of the evidence, that each of its various claims are compensable. For each of those claims that we may find to be compensable, Monsanto also has the burden of proof as to the amount of the compensation to which it may be entitled to recover.

Monsanto’s claims are summarized in SOC Exhibit 1, as updated. Monsanto divides its claims into two major categories: (1) Base Data Costs for Glyphosate, and (2) Additional Compensation Elements.

Base Data Costs is comprised of five subcategories with claim amounts as follows:

Technical and End-Use Data (SOC Exhibit 2)	\$ 18,082,165.00
Roundup Ready Registration Related Data (SOC Exhibit 3)	\$ 12,451,000.00
Label Development Data Including	
Weed Resistance (SOC Exhibit 4)	\$ 15,095,482.00
Regulatory Management Costs	\$ 3,616,433.00
EPA Tolerance Fees	<u>\$ 147,375.00</u>
The total of the above claimed amounts is:	\$ 49,392,455.00

Additional Compensation is comprised of two subcategories with claim amounts as follows:

Interest	\$ 38,470,397.00
Premium	\$ 65,897,139.00

The interest amount is based on three components of Base Data Costs:

- (1) Exhibit 2 Studies but excluding those as to which the amount was based on estimates provided by Monsanto expert, Bernalyn McGaughey. The interest amount claimed for such studies is \$36,865,410.93;
- (2) Exhibit 4 Studies but only those included as Additional Studies. The amount of interest claimed for those studies is \$1,447,852.23; and,

(3) Tolerance Fees with a claimed amount for interest of \$157,133.55.

The total claimed amount, including the Interest and Premium components with the total of Base Data Costs, is \$153,759,990.00.

According to Monsanto, Ritter's allocable share of this amount, based on Monsanto's application of a "per capita" allocation approach, is \$7,688,000.00.²

Ritter has stipulated to the compensability (although not to the amount) of a number of studies included in SOC Exhibit 2 but otherwise disputes Monsanto's claims in this proceeding. Ritter seeks to limit its compensation obligation in this proceeding to "less than \$100,000" (Ritter Reply at 1) while still having had, and continuing to have, the right to sell and market glyphosate especially for use on glyphosate tolerant crops. Based upon the evidence presented to us, this clearly would be contrary to the requirement that it pay its "fair share" of the allowable costs which Monsanto has incurred. This does not mean, however, that Monsanto should recover as claimed "costs" amounts which should not properly be recovered under FIFRA.

2. SOC Exhibit 2 Claims

SOC Exhibit 2 contains a list of 172 studies which have sometimes been referred to by Monsanto in this proceeding as "core" studies. They are studies which Monsanto maintains were required by EPA, pursuant to the Part 158 guidelines, for Monsanto to secure its glyphosate-tolerant registrations or to maintain those registrations. Monsanto seeks to recover \$18,082,165.00 for these claimed data costs before allocation of a portion thereof to Ritter.

² Monsanto arrived at this amount based on its position at the hearing that twenty (20) entities (although it had presented a list of twenty-one (21)), including itself, have active glyphosate technical registrations and should be deemed to equally share the costs claimed by Monsanto in this proceeding. In its post-hearing reply brief, dated April 5, 2013 ("Monsanto Reply"), Monsanto adjusted this number to twenty-three (23) entities, which would result in a reduction of its claim amount. Monsanto Reply at 39-40. Application to this case of a "per capita" allocation approach is discussed in greater detail herein.

SOC Exhibit 2 has nine columns labeled as follows: Study No., MRID No., Study Title, 3rd Party Cost, Expert Estimate of Study Cost, Internal Man-Months, Annual FTE Cost, Monsanto Manpower Cost and Base Study Cost. The SOC Exhibit 2 studies also are listed in Monsanto Exhibit 25. The eight columns of this exhibit are labeled: Ritter (referring to exhibit numbers for the studies as used in this proceeding), MRID No., Study Title, GDLN No. (OPP/OPP TS) (referring to applicable guideline numbers; EPA has a harmonized guideline numbering system with the prefix OPPTS that in some cases has replaced its older guideline identification system so the same guideline may be in the 70 Series and in the OPPTS 850 Series), Subm. Date (referring to study submission dates to EPA), Tolerance Petition/MON Label (referring to tolerance petitions or amendments and Monsanto's label), Compensability Documentation (MON Numbers) (referring to record evidence relied upon by Monsanto as to compensability) and Comments (referring to Monsanto's views as to, e.g., the purpose and/or significance or other information supporting compensability of the studies). Monsanto Exhibit 26, in three volumes, contains Monsanto's supporting documentation for the studies listed in Exhibit 25.

Exhibit 25 was prepared by Ms. Bernalyn McGaughey, who testified at length as Monsanto's principal regulatory expert in the case. Ms. McGaughey is the President and CEO of Compliance Services International, a consulting firm in Tacoma, Washington. She has forty years of scientific and regulatory experience in data evaluation, research, study monitoring and project management related to the properties, use, toxicology and environmental fate of pesticides and other chemicals. Her experience includes original and regulatory research, report design and composition and international technical assistance in toxicology investigations and risk assessments. She is especially experienced in EPA and other regulatory affairs, endangered species and data compensation matters. She has worked with and assisted original data submitters in determining the scope of their data compensation obligations. She also has worked with and assisted follow-on applicants in determining the scope of their data compensation obligations.

In opposing compensability of the disputed studies, Ritter relied principally on the testimony of its regulatory expert, [REDACTED] together with supporting materials in Monsanto Exhibit 26 and also Ritter Exhibits 1088 and 1095. [REDACTED] is the principal of another regulatory consulting firm called [REDACTED] has advised and assisted a number of follow-on applicants in glyphosate and other registration matters.

Exhibit 1088 is a summary prepared by [REDACTED] regarding [REDACTED] positions as to compensability of disputed SOC Exhibit 2 Studies.

a) Stipulated Studies

Ritter has stipulated that the following studies in SOC Exhibit 2 are compensable but disputes the amounts claimed by Monsanto as compensation for those studies:

Nos. 2, 3-7, 11-19, 24-25, 29, 30-47, 64-70, 74, 84, 87-90, 94-95, 98-99, 103, 110-111, 113, 116, 123-124, 150, 153 and 167-172. Ritter Ex. 1088.

Accordingly, these studies will not be further addressed as to the threshold question of compensability.

b) Disputed Studies

Ritter opposes the compensability of the studies discussed below on various grounds. We will address the potential compensability of these studies in the manner in which they were grouped in the categories as initially listed by Ritter at the hearing.³ Our discussion, where helpful to our analysis, will

³ We note that in [REDACTED] Demonstrative Exhibit C, Ritter grouped the disputed studies in categories which were labeled in a different way, *i.e.*, Not Identical or Substantially Similar to Ritter's Products, Not Identical or Substantially Similar to Ritter's Uses, Not Required When EPA Granted Ritter's Registrations, Not Considered by

address Monsanto's principal arguments and evidence in support of compensability of the studies. We also will address, where helpful to our analysis, Ritter's principal arguments and evidence as to why the studies are not compensable.

i. Environmental Fate Studies (Study Nos. 1, 10)

Study No. 1 is a so-called "environmental fate" study. Ms. McGaughey testified that it addresses a Part 158 data requirement and otherwise opined that it was compensable. It appears that the only basis on which Ritter disputes Study No. 1 is that it is claimed to be outside of the 15-year allowable period of compensability. Ritter argues that the "cite-all" provisions at Section 152.86 allow the applicant to rely upon data "in effect on the date EPA approves the applicant's present application." See 40 C.F.R. 152.86(d)(2)(ii). According to Ritter, this means that the 15-year period of compensability starts when the registration is granted and goes back 15 years. As Ritter secured its first glyphosate registration on February 9, 2005, and the study was submitted on December 22, 1989, Ritter asserts that it does not come within the 15-year period. Ritter Brief at 73-74.

Ritter claims that one of Monsanto's regulatory experts, Rick Tinsworth, and also agreed that the compensability period is computed from the approval date of Ritter's first registration, i.e., February 9, 2005 and thus closed on February 9, 1990. The cited hearing testimony of Mr. Tinsworth does not reflect such agreement. He merely agreed with Ritter's counsel's leading characterization that the date of approval of an application was "important." He was not asked, and did not say, why it was important. There is no basis for an inference that his agreement as to "importance" related to computation of the 15 year cut-off. Further, although supportive of Ritter's position, the testimony of [REDACTED] was based on the premise that Mr. Tinsworth had agreed with Ritter's position

EPA, Submitted Over 15 Years Before Ritter's First Registration, and Public Literature or Government Generated. Our discussion of the disputed studies, as appropriate, takes these characterizations into account.

that the fifteen year period is based on the approval date, not the application date. testimony cannot be given persuasive weight in those circumstances.

Monsanto asserts that the 15-year period relates back to November 9, 1989 (Monsanto Reply at 11, fn. 14), or 15 years from the date Ritter filed its initial application on November 9, 2004. According to Monsanto, the 15-year period runs forward from the date data are submitted by the original data submitter in support of a registration application and runs backward from the date of the initial application by a follow-on applicant. Monsanto Brief at 39.

Other FIFRA arbitrators have wrestled with the question of when, particularly in “cite-all” method cases, the 15-year period properly runs. Although we do not find our views on this question to be entirely free from doubt, we believe that the better view was expressed by Arbitrator Charnoff. See Avecia, Inc. and Mareva Piscines et Filtration’s, S.A., No. 23-171-00170-99 Award as Amended (August 29, 2002) wherein he cited his ruling of October 29, 2001 on this issue. This view is to consider the 15-year period based on the follow-on’s application date rather than the registration date. Our view finds support in FIFRA as it provides that EPA may “consider” data “within the fifteen-year period following the date the data were originally submitted only if there has been an offer to compensate the original submitter.” 17 U.S.C. 136a(c)(1)(F)(iii).

We also find support in Section 152.93(b)(c) of the regulations: [T]he applicant may cite any valid study without written authorization from, or offer to pay to, the original data submitter if . . . [t]he study was originally submitted to the Agency on or before the date that is 15 years before the date of the application for which it is cited . . .” Although this EPA regulation concerns use of the “selective” method, it does not seem logical to treat this issue differently simply because an applicant elected to proceed under the “cite-all” method. EPA’s consideration as to the potential registrability of a follow-on’s application begins on the date the application is submitted. This is true whether the studies upon

which it relies are specifically identified as part of the “selective method” application or more generally relied upon as part of the “cite-all” method application.

We note that Ms. McGaughey opined that the application date is the correct date “[b]ecause that’s the date that EPA begins to rely on the data that underlie that application.” (Tr. 1888:17-1889:6). Although this question is largely one of law, we found her opinion to be entitled to considerable weight, especially given the above-cited provisions of FIFRA and Section 152.93(b)(c) and our belief that interpretive questions such as this one should be addressed in a logical and consistent way to the extent reasonably possible.⁴

Accordingly, we find that Study No. 1 is compensable.

Ritter opposes compensability of Study No. 10, a storage stability study, since it was allegedly not reviewed, considered or relied upon by EPA. Other Ritter arguments include that there was no applicable Part 158 guideline for this kind of study. See Ritter Brief at 64. The 1989 unpublished Monsanto study, entitled “Storage Stability of Glyphosate in Environmental Water: Lab Project Number: MSL-8626:1005,” was submitted to EPA and bears an MRID number. Ms. McGaughey testified that it was an environmental fate study which addressed Part 158 data requirements and was, therefore, compensable. Upon review of her testimony and the other evidence of record, and consideration of Ritter’s arguments, we reasonably infer that the study was reviewed, considered and relied upon EPA and otherwise find this study to be compensable.

⁴ We are mindful that other FIFRA panels, including ones on which members of this panel have participated, have reached a different conclusion as to when the 15-year period runs. In so doing, they relied in part on comments made by EPA in the preamble to the regulations implementing the compensation provisions of FIFRA. See 44 Fed. Reg. at 27949 (May 11, 1979) (“The statute places in the non-compensable category all data submitted to the Agency or its predecessors prior to January 1, 1970 (and all data submitted more than 15 years before the approval of the application in question. . .”). This language was also reiterated by EPA when the regulations (after being struck down for unrelated reasons) were reissued. 47 Fed. Reg. at 57643 (Dec. 27, 1982). For the reasons previously indicated, however, and based on the record presented here, we find EPA’s “parenthetical” comment to be troubling since it is inconsistent with other more persuasive authority regarding this issue.

ii. Non-Target Organism Studies (Study Nos. 56, 57, 58, 59, 60, 61, 62, 63, 78-79, 91, 92, 93, 100, 101, 102, 104, 105, 107, 118, 119, 120, 121, 122, 127, 128, 129, 130, 131, 132, 133, 134, 135, 136, 137, 138, 139, 140, 141, 142, 144, 145, 146, 147, 148, 149 and 152.)⁵

We begin our discussion with Study No. 152, the California Red-legged Frog Assessment (the “CRLF Risk Assessment”). Ritter argues that this study is not compensable “data” covered by Part 158. Rather, says Ritter, it is, according to the study title, non-compensable “information” to support an assessment under the Endangered Species Act, 16 U.S.C. 1531 *et seq.* (“ESA”) for the red-legged frog. Ritter also argues that the study along with a number of other studies referenced in the CRLF Risk Assessment, was not reviewed, considered or relied on by EPA for registration purposes and was prepared by EPA to satisfy settlement obligations it had in a California lawsuit. According to Ritter, EPA’s obligations under ESA are separate and distinct from EPA’s obligations to decide FIFRA applications. Under FIFRA Sec. 3(c)(5), which includes no data compensation provision, EPA conducts ecological risk assessments. Under FIFRA Sec. 3(c)(1), which includes a data compensation provision, applicants obtain registration for pesticides if they do not cause unreasonable effects to the environment. Ritter acknowledges that there may be some overlap in these EPA responsibilities. However, Ritter contends that EPA’s activities under these two sections are basically separate responsibilities. Ritter Brief at 17-18, 50-51.

We do not find Ritter’s arguments to be persuasive. Ms. McGaughey testified that the CRLF Risk Assessment was an effects determination generated by EPA for purposes of registration of glyphosate under FIFRA in order to assess the risks posed by the use of glyphosate on the CRLF, an endangered species. EPA expressly stated that “[the purpose of this assessment is to evaluate potential direct and

⁵ Ritter lists Study Nos. 154-166 as disputed Acute Toxicity Studies although some, we believe, also may be viewed as Non-Target Organism Studies. Ritter also includes Study Nos. 56-63 as disputed “AMPA” studies.

indirect effects on the California red-legged frog . . . arising from the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) regulatory actions regarding use of glyphosate. . .” (Ex. 26, Tab 78, at MONO82305). We find that EPA’s citation of various studies in the CRLF Risk Assessment shows, as Ms. McGaughey also testified, that EPA also used those studies to support the registration of glyphosate.

The ESA requires that all federal agencies ensure that regulatory actions they take within their own statutory authority are conducted so as not to harm endangered species. Consistent with that requirement, FIFRA independently requires EPA to assess the effects of the use of a pesticide on non-target organisms (i.e., ones that may be incidentally exposed to a pesticide), such as the California red-legged frog, in regulating and registering pesticides under FIFRA to protect endangered species. EPA’s risk assessment process is the means by which EPA evaluates data for purposes of registration.

Applicants for pesticide registration are required to generate data, or cite to another party’s data, so that EPA can assess potential hazards to non-target organisms. 40 C.F.R. 158.130(e); see also FIFRA Sec. 3(c)(5), 7 U.S.C. 136a(c)(5) and FIFRA Sec. 2(bb)(1), 7 U.S.C. 136(bb). EPA then analyzes that data and conducts a risk assessment to determine whether non-target organisms may be harmed by the use of a pesticide. After conducting an ecological risk assessment under FIFRA, EPA’s conclusions are listed in an effects determination. See 70 Fed. Reg. at 66,394. Depending on the outcome of the assessment, EPA may then be required to consult formally with other government departments which administer the ESA.

Accordingly, we find that EPA required and relied on data in the CRLF Risk Assessment for purposes of Ritter’s glyphosate registrations. Therefore, Study No. 152 is compensable. That the CRLF Assessment also was used in the California litigation does not change this result. See, e.g., 40 C.F.R. 158.80(b) (“[D]ata developed for purposes other than satisfaction of FIFRA data requirements . . . may also satisfy data requirements in this part.”) As recognized in DowElanco and The Trifluralin Data Development Consortium and Albaugh, Inc., Case No. 52 Y 171 00100 95 (June 1, 1998) at 6-7: “This

issue is not why the study was submitted, but whether it was one which would have been 'required' as of the key date. Similarly, whether the study was done in or for a state, e.g., California, or foreign country, is, in and of itself, immaterial. . . Why it was submitted by the Claimant is immaterial. . . The issue is whether it was the type of study the EPA required as of the date the registration was granted."

Study Nos. 91, 92 and 93 are referenced in the CRLF Risk Assessment and are compensable for the above reasons. This finding also is supported by the testimony of Ms. McGaughey. Ritter also argues that the studies are not compensable since they concerned a Monsanto end-use product called Roundup Ultra, not technical grade glyphosate. Ritter Brief at 64-65. However, as indicated, the studies were referenced in the CRLF Assessment and are compensable for this reason. Moreover, as further discussed herein, the active pesticide ingredient in the various glyphosate salts and end-use products is the acid. The record confirms that this is what EPA cares about for registration purposes. It treats all of the salt forms the same for registration (and also tolerance) purposes.

Study Nos. 100, 101 and 102 also are referenced in the CRLF Risk Assessment and are compensable for the above reasons. This finding also is supported by the testimony of Ms. McGaughey. Here, also, Ritter argues that the studies are not compensable since they concerned Roundup Ultra (Ritter Brief at 65-66), an argument we have already rejected. Ritter further argues that that the studies are not compensable since they tested the toxicity of Roundup Ultra on Roundup Ready Rice, the glyphosate use for which has not been approved by EPA. Ritter Brief at 66. The studies, however, also would have applied to conventional rice, which is included on Ritter's glyphosate label.

A number of other disputed non-target organism studies, and other studies listed in SOC Exhibit 2, were used by EPA in the CRLF Risk Assessment and are, therefore, compensable for the reasons previously stated. These compensable non-target organism studies are: Nos. 56-58, 60, 62, 78, 106, 107, 118, 119, 120, 121-122, 127, 129, 133, 134-139, 140, 141, 142, 144-145 and 147-149. We note that some of these studies "overlap" since they are also listed in other categories of studies disputed by

Ritter (e.g., Study Nos. 56-58, 60 and 62 are also included in the category of “AMPA Studies”). As appropriate, we will also address them herein. We again note that Monsanto’s characterization of some of these studies as “additional” or “supplemental” does not preclude compensability if they are otherwise found to be compensable.

We turn now to disputed Study Nos. 78 and 79. Study No. 78 is entitled “Acute Toxicity of a Herbicide (Roundup) to Selected Frog Species: Final Report.” It was a 1995 unpublished non-target organism study prepared by Curtin University of Technology in Australia. Monsanto has not claimed any compensable cost for Study No. 78 in this proceeding. Accordingly, it did not need to be disputed by Ritter.

With regard to Study No. 79, as with all of the SOC Exhibit 2 studies, it was submitted to EPA and bears an MRID. Although Monsanto did not conduct the study or prepare Study No. 78, Monsanto prepared Study No. 79 in which it considered and reviewed Study No. 78 for risk assessment purposes and clarified how the endpoints of the study should be calculated for EPA. Monsanto submitted Study No. 79 to EPA in support of its glyphosate registration. The costs claimed are limited to that involvement. With this understanding, we find the study to be compensable.

We find that Study Nos. 104 and 105 are also compensable non-target organism studies. Study No. 104 is an unpublished Monsanto study entitled “Testing Toxicity to Beneficial Arthropods(sic) Cereal Aphid Parasitoid-Aphidius rhopalosiphii: (Roundup Ultra Herbicide): Lab Project Number: 95 10 48 054:080694.” Study No. 105 is an unpublished Monsanto study entitled: “Testing Toxicity to Beneficial Arthropods (sic) Predacious Mite-Typhlodromus pyri: (Roundup Ultra Herbicide): Lab Project number: 95 10 48 056.” Ritter argues that there is no documentation to suggest that EPA ever reviewed, considered or relied upon these studies. Ritter Brief at 54. We disagree. These 1998 studies were submitted to EPA, have MRIDs and, given the subject matter of the studies, we reasonably infer

that they were reviewed, considered and relied upon by EPA for glyphosate registration and registration maintenance purposes.⁶

As for Study No. 143, Ritter claims that it was conducted by Batelle Labs and sponsored by the State of Washington. According to Ritter, Monsanto's compensation claim for this study is simply based on its repackaging the study and being the first to submit it to EPA. The evidence shows, however, that Monsanto was the actual sponsor of the study as confirmed by the testimony of Ms. McGaughey, who had "first hand involvement" with the study. Tr. 2715:7-2716:12. Crucially, the evidence also shows that Monsanto's claim is limited to its own costs for participating as sponsor in the study.

Finally, although included by Monsanto in this category, we will address Study Nos. 59 and 61 in our consideration below of the AMPA category of disputed studies.

iii. Worker Exposure Studies (Study Nos. 8, 9)

These unpublished 1990 Monsanto studies are 192 pages (Study No.8) and 167 pages (Study No. 9). They are, respectively, entitled: "Assessment of Forestry Nursery Workers Exposure to Glyphosate during Normal Operation: Lab Project: MSL-9655" and "Assessment of Forest Worker Exposures to Glyphosate During Backpack Follar Application of Roundup Herbicide: Lab Project Number: MSL 9655." Ritter opposes compensability of these studies since Monsanto referred to them as "additional data" at the time they were submitted to EPA. According to Ritter, this confirms that the studies were not required by EPA. Ritter Brief at 44.

Ms. McGaughey testified that the studies are compensable. She also testified that studies submitted as "supplemental" or "additional" data and/or classified as such can be compensable so long

⁶ Study Nos. 104 and 105 are also compensable Section 6(a)(2) studies as discussed below.

as they meet the criteria for compensability under 40 C.F.R. 152.86. As also discussed above, we reject Ritter's claim that the characterization of data at the time it is submitted, e.g., as "additional" is determinative as to whether it is required and compensable. In any event, we find that Study Nos. 8 and 9 clearly were required as "EPA requires applicator/user exposure data for all pesticides to evaluate potential risks to people applying the pesticide. . ." See *Data Requirement for Pesticide Registration* http://www.epa.gov/pesticides/regulating/data_requirements.htm (page 5 of App. 41 to Ritter's Brief).

Accordingly, Study Nos. 8 and 9 are compensable.

iv. FIFRA Section 6(a)(2) Studies (Study Nos. 71, 78, 79, 125, 126)

Study No. 71, a 34-page 1995 Monsanto study, is entitled: "A Comparative Study of MON 2139, MON 60603, and MON 52276 on Cardiovascular Function in Beagles." It was submitted to EPA with a July 20, 1995 letter to EPA's Office of Pesticide Programs and bears an MRID.

Ritter opposes compensability of Study No. 71 as not required by EPA, or reviewed or relied upon by EPA, to support Monsanto's registration. Ritter asserts that there is no Part 158 guideline for this kind of study and that the subject matter is just part of EPA's overall risk assessment work. According to Ritter, since the study was submitted as a Section 6(a)(2) study, it was not required for a Section 3 registration. Ritter Brief at 52-53. Ritter in large part disputes the compensability of Study Nos. 78-79 and 125-126 for similar reasons.

We do not agree with Ritter. Section 6(a)(2) of FIFRA states: "If at any time after the registration of a pesticide the registrant has additional factual information regarding unreasonable adverse effects on the environment of the pesticide, the registrant shall submit such information to the Administrator." (emphasis added). 7 U.S.C. 136d(a)(2); see also 40 C.F.R. 159.152. Accordingly, a registrant is required to submit such information to EPA.

EPA has recognized that the goal of Section 6(a)(2) is to "ensure that EPA promptly receives any data indicating [sic] that might lead EPA to conclude use of a pesticide may pose unreasonable adverse

effects.” 50 Fed. Reg. 38,115, 38,116 (Sept. 20, 1985). The Agency has further recognized that Section 6(a)(2) “provides an important function by assuring that a previous Agency decision to register a pesticide remains a correct one, and that a registered pesticide can in fact be used without posing unreasonable adverse effects to human health and the environment.” 62 Fed. Reg. 49,370 (Sept. 19, 1997). It is important to bear in mind that EPA’s powers under FIFRA are exercised by granting registrations and maintaining them in effect. Under this statute, EPA does not have authority to direct a registrant as to how to conduct its business. Rather, it grants a registration if the product meets the FIFRA standard and cancels the registration if it does not.

Further, as required by EPA regulations regarding registration data requirements, “[a]n applicant shall furnish with his application any factual information of which he is aware regarding unreasonable adverse effects of the pesticide on man or the environment, which would be required to be reported under FIFRA Sec. 6(a)(2) if the product were registered.” 40 C.F.R. 152.50(f)(3); 40 C.F.R. 159.152(b). These data are used by EPA in its risk assessment process to determine whether a pesticide meets the statutory standard for registration. See Overview of the Ecological Risk Assessment Process, at 29 (Jan. 23, 2004).

At the hearing, Ms. McGaughey testified as to the compensability of each of these studies. She also testified that EPA reviews Section 6(a)(2) data, together with any rebuttal data submitted by the registrant, to determine whether it impacts EPA’s determination to maintain a pesticide’s registration. Her testimony was not contradicted.

It is clear that Section 6(a)(2) is essentially a way for EPA to secure important information regarding the continuation of a registration, something which is of critical importance not only to an original registrant but also to a follow-on such as Ritter. Section 6(a)(2) data and the rebuttal data are compensable because they are required by EPA with regard to whether a registration can be

maintained. Also, Ritter's regulatory expert, testified on cross-examination that Section 6(a)(2) data can be compensable:

Q. Data submitted under section 6(a)(2) can be compensable; correct?

A. Yes.

Q. So just because data are submitted under section 6(a)(2) does not mean that there is a bar to the compensability of that data; correct?

A. No. 40 C.F.R. part 152.83 specifically identified data in support of an application for registration, amended registration, re-registration or experimental use permit, et cetera.

Q. So that would include data submitted under section 6(a)(2); correct?

A. Yes. And I mentioned that earlier.

Q. I just want to make sure I heard correctly.

A. Right.

Tr. at 4667:8-4668:1.

The record, therefore, establishes that Study Nos. 71, 78, 79, 125 and 126 were submitted by Monsanto under Section 6(a)(2) to rebut adverse effects and/or were used by EPA to assess the continued registration of glyphosate. For all of the above reasons, the studies are compensable.

v. Residue Tolerance/Import Tolerance Studies (Study Nos. 20-23, 26-28, 72-73, 75-77, 80-83, 85-86, 96-97, 112, 114, 115, 117 and 143)

We begin our consideration of these disputed studies with some background regarding the potential compensability under FIFRA of tolerance data, including import tolerance data. Another Monsanto regulatory expert, Rick Tinsworth, a former manager at EPA, provided some useful testimony in this regard.

EPA regulates pesticides under two statutes, FIFRA and the Federal Food, Drug, and Cosmetic Act ("FFDCA"). A "tolerance" is the total amount of legally permissible pesticide residue on a food item

for every food crop use of a pesticide. EPA is authorized under FFDCA to establish, modify, or maintain tolerances for pesticide residues in or on food. See 65 Fed. Reg. 35,069, 35,071 (June 1, 2000). Under Section 408 of FFDCA, EPA is required to establish tolerances for pesticides at levels that are “safe” and to ensure that those levels continue to be safe over time.

The Food Quality Protection Act (“FQPA”) amended both FIFRA and FFDCA. It established a single health-based safety standard under section 408 of FFDCA for the use of pesticides on food, i.e., a standard that there is a reasonable certainty of no harm. 65 Fed. Reg. at 35,071. The registration test for a pesticide under FIFRA was revised to include this reasonable certainty of no harm standard. In assessing the registration of a pesticide, FQPA also required EPA to assess the aggregate exposure of a pesticide from all exposures other than occupational. These included dietary exposure (adding together exposure from any proposed new food use and all existing food use exposures), drinking water exposure and exposure from consumer uses. 65 Fed. Reg. 35,071. FQPA also made explicit that data supporting a tolerance are compensable under FIFRA. FFDCA 408(i)(1), 21 U.S.C. 346a(i)(1).

In order for EPA to determine the aggregate exposure to a pesticide, it conducts a “risk assessment.” To conduct such an assessment, before EPA can register a new use of a pesticide on a particular food crop (such as a glyphosate-tolerant crop), EPA requires exposure data. EPA will not issue a registration for the use of a pesticide on a food crop unless and until a tolerance is established based on a new aggregate exposure assessment. See 40 C.F.R. 152.112(g). EPA also requires exposure data in order to change or amend a tolerance. This type of data is generated by field residue studies which are designed to produce the maximum residues under the existing or proposed product label. 73 Fed. Reg. 29,456, 29,458 (May 21, 2008). It is clear that data submitted to support a new tolerance, or to support an amendment of an existing tolerance, are compensable under FIFRA and FFDCA.

Monsanto maintains that the aggregate exposure risk assessment required by the FQPA amendments must include not only pesticide residues on food grown in the United States but also

pesticide residues on food grown outside the United States and then imported. Monsanto Brief at 45-46. According to Monsanto, a pesticide residue on imported food must conform with a tolerance or tolerance exemption established by EPA. An import tolerance is the residue level of a pesticide allowed on an imported food item. "There is no statutory or regulatory distinction between an 'import tolerance' and any other tolerance issued by EPA." 65 Fed. Reg. at 35,070; Pesticide Registration Manual, Chapter 11 – Tolerance Petitions, at 3, (www.epa.gov/pesticides/bluebook/chapter11.html). Also citing Ms. McGaughey's testimony, Monsanto maintains that data submitted to support an import tolerance is compensable under FIFRA and FFDCA and that all of the disputed documents in this category are compensable. Monsanto Brief at 46.

Ritter vigorously disputes Monsanto's position as to the compensability of these studies. It argues that only domestic tolerances, and not import tolerances, are compensable under FIFRA because only domestic tolerances are required for registration. Ritter Brief at 37-41. We disagree. We find nothing in the law which supports Ritter's position. Rather, as EPA has indicated, "[t]here is no statutory or regulatory distinction between an 'import tolerance' and any other tolerance." 65 Fed. Reg. 35,069, 35,070 (June 1, 2000). Ritter relies on the absence of foreign locations for crop field trials in EPA's 1996 Residue Chemistry Test Guidelines and makes other arguments to support separate treatment of import tolerances for compensability purposes. We do not find its analysis to be persuasive. Ritter Brief at 40.

In this regard, Ritter also claims that import tolerances should be treated differently because they are required under FFDCA Sec. 408(e) while domestic tolerances are required under a different provision, FFDCA Sec. 408(i). Ritter Brief at 39. However, Ritter is "splitting hairs" here. The data compensation provision in FFDCA Sec. 408(i) does not make such a distinction. Rather, it generally applies data compensation to all data and information submitted to EPA "in support of a tolerance or an exemption of a tolerance." FFDCA Sec. 408(i), 21 U.S.C. 346a(i)(1).

Ritter also points to the fact that it has no foreign glyphosate registrations, while Monsanto does. It asserts that it makes sense, therefore, that Monsanto would be interested in imported food products and would have generated data to set import tolerances and tested foreign residues. Ritter maintains, however, that it has no uses on its labels for imported food products, only domestic application on domestic crops, and that EPA tolerances are only required for each use on the product label that it considers for registration in the United States. Ritter Brief at 38-39.

We agree with Monsanto that it does not matter for compensability purposes whether or not a party's label includes imported food products. Just as Ritter's label does not include imported food products, neither does Monsanto's. Rather, what does matter is whether the data supporting the import tolerance are required for the registration of the uses that are on Ritter's label. 40 C.F.R. 152.86(d)(2)(ii). As discussed above, the FQPA amendments to FIFRA require EPA to conduct an aggregate exposure and risk assessment that includes pesticide residues on food grown outside the United States and then imported. Tolerance data on imported food are, therefore, required for the registration of domestic uses on food crops, and Ritter has food crop uses on its labels. We note in this regard that [redacted] agreed that an import tolerance has a direct impact on Ritter's glyphosate registration due to EPA's aggregate exposure risk assessment under FQPA.

Ritter also argues that foreign residue data, and data generated outside the United States, are not compensable. Ritter Brief at 40-41. Ritter claims that although this kind of data may be important to Monsanto's business purposes, such data are not important as to Ritter's FIFRA registration obligations. However, this kind of data may be considered by EPA in support of a registration. 40 C.F.R. 158.80(a) ("field study data developed outside the United States may be submitted in support of a pesticide registration . . . [o]nce submitted, the Agency will determine whether or not the data meet the data requirements.") Also, [redacted] acknowledged that EPA has complete discretion to use foreign residue data in granting or maintaining a U.S. registration.

We agree, as Ms. McGaughey testified, that if EPA relies on the foreign residue data in support of a registration, the data would be compensable. The record, including reasonable inferences we have drawn, supports Monsanto's position that EPA relied on the data in the disputed studies in this category for the registration of glyphosate. Accordingly, we find that they are compensable.

Ritter has raised other arguments in opposing compensability of the studies in this category. We do not find them to be persuasive. For example, with regard to Study Nos. 21, 112, 118-120, we have already found that simply characterizing data as "supplemental supporting data" does not make it non-compensable. With regard to Study No. 80 and the accompanying Study Nos. 81-83, 85 and 86, Monsanto's reference, in submitting the data, to an unrelated subject (preventing possible trade barriers between the United States and Canada) does not render the studies non-compensable.

Ritter asserts that Study Nos. 80-83, 85 and 86 are not compensable because they do not relate to uses on Ritter's label. However, the record indicates that these data were used to set tolerances for the use of glyphosate on oats, and [REDACTED] testified that the use on oats is included on Ritter's label. The studies are compensable. Ritter claims that Study Nos. 20-23 are not compensable since they were rejected by EPA, and that Ms. McGaughey agreed. However, Ms. McGaughey testified that the studies were neither rejected nor incomplete but were part of the data used by EPA to address the data requirement. These studies were shown to be compensable.

Ritter correctly points out that Study Nos. 114, 115 and 117-122 concerned Roundup Ready rice and Roundup Ready wheat. Those crops are not on Ritter's label. Indeed, those uses of glyphosate have not been approved by EPA. Ritter Brief at 61-62. However, the record supports our finding that these data also support the use of glyphosate on conventional wheat and rice. These uses are on Ritter's labels and are otherwise compensable. Further, as Monsanto has noted, EPA included these data in its cotton risk assessment, and cotton also is on Ritter's label. See 69 Fed. Reg. 65,081, 65,082 (Nov. 10,

2004) (“the proposed tolerance for [Roundup Ready] . . . rice . . . [and] wheat . . . are included in the risk assessment”).

Finally, although included by Ritter in this category, we believe that Study Nos. 96 and 97 are more appropriately considered below in our discussion of the claimed compensability of the “AMPA” studies.

Accordingly, for the above reasons, we find that all of the disputed studies in this category (except for Study Nos. 96 and 97 which we discuss below) are compensable inasmuch as they supported new tolerances or tolerance amendments.

vi. “AMPA” Studies (Study Nos. 48-63; also, 96-97)

In our ruling on the Motion to Strike, we denied Ritter’s request that we strike Study Nos. 48-63. We determined that there were a number of material facts in dispute regarding these studies and that we would benefit from a more fully developed record in further considering the claimed compensability of the studies. See Ruling on Ritter’s Motion to Strike Portions of Monsanto’s Claim, dated April 9, 2012, at 9.

By way of background, these studies concern a break-down product or metabolite of glyphosate called aminomethylphosphoic acid, or “AMPA.” In establishing tolerances, EPA analyzes the anticipated residue levels of a pesticide or its metabolites and then decides which metabolites “are of concern and need to be included in the tolerance expression” as separate components. If EPA determines that certain pesticide metabolites are not of concern, they are not separately identified in the tolerance expression.

Until 1996, AMPA was a separate, independent component in EPA’s tolerance expression for glyphosate. However, in September 1993, EPA reassessed glyphosate tolerances as part of its registration review process and proposed to treat AMPA as equivalent to glyphosate in the glyphosate tolerance expression and no longer treat it as a separate component. In this general time frame,

Monsanto had been developing its glyphosate-tolerant crops. It does not appear, however, that EPA's proposal to remove AMPA from the tolerance expression had taken into account the possible implications for residue tolerance purposes of such removal with regard to applying glyphosate to glyphosate-tolerant crops.

Monsanto met with EPA in February, 1994 to ensure that EPA was aware that the toxicological studies Monsanto had performed in developing its glyphosate-tolerant crops had shown that AMPA was a "greater component of the total residue." Monsanto presented an overview of those studies in that meeting. Ex. 35. In response to the "new information", EPA indicated that it would "not change [its] recommendation to remove AMPA from the tolerance expression" subject to there being "no unexpected results in the final reports." Ex. 41.

Monsanto then submitted Study Nos. 48-63 to EPA with a transmittal letter dated August 5, 1994. In that letter, Monsanto stated that it was submitting the studies as supplemental information and "... not to satisfy any regulatory requirement, but rather as part of Monsanto's commitment to product stewardship." Ex. 25, Tab 48, Ex. 26, Tab 48. The studies were accepted by EPA and received MRIDs.

The evidence supports that EPA reviewed the studies and found them to be "acceptable" and concluded in February 1996 that they supported EPA's decision to remove AMPA from the tolerance expression. Id. Thereafter, in June 1996, EPA published a proposed rule to re-characterize AMPA in the tolerance expression as equivalent to glyphosate, and not as a separate component. See 61 Fed. Reg. 33,469, 33,471 (June 27, 1996). By 1998, AMPA had been removed as a separate component of the tolerance expression for glyphosate.

It is undisputed that AMPA had been removed from the tolerance expression years before Ritter secured its initial registration in 2005. Pursuant to Section 152.86(d), it would appear, therefore, that the disputed studies in this category were not "the types of data that EPA would require to be submitted

... under the data requirements in effect on the date EPA approves the applicant's present application."

The record indicates, however, that the disputed studies were submitted to EPA and received MRIDs. EPA considered them in determining whether, despite Monsanto's use of glyphosate on glyphosate-tolerant crops, its proposed removal of AMPA from the tolerance expression should be disturbed.

It may have been prudent for Monsanto to have conducted the studies in connection with introduction of its glyphosate-tolerant crops. The studies were reviewed and of apparent interest to EPA. However, there is no indication in the record that EPA requested or required the studies. Monsanto argues that the data it provided in Study Nos. 48-63 relieved Ritter and other follow-on applicants of the obligation to prove to EPA that removal of AMPA from the tolerance expression should not be altered due to the introduction of the use of glyphosate on glyphosate-tolerant crops. Monsanto Brief at 48-49.

The studies could have been helpful to EPA regarding its proposed removal of AMPA from the tolerance expression, particularly given the "changed circumstances" resulting from the use of glyphosate on glyphosate-tolerant crops. (For the reasons previously provided, we do not agree with Ritter that the studies are not compensable simply because they were characterized as "supplemental".) However, we find that Monsanto has not met its burden of proof that EPA would have required the data to be submitted by Ritter, or by any other applicant, if Monsanto had not submitted it. That contention is too speculative given the evidence before us. We find, therefore, that the disputed AMPA studies, i.e., Study Nos. 48 – 63 as they concerned EPA's decision to remove AMPA from the tolerance expression, are not compensable.

However, with regard to Study Nos. 56-58, 60 and 62, we previously concluded that they are compensable non-target organism studies since they were cited in the CRLF Risk Assessment. Accordingly, on this separate basis, the studies are compensable. We note that EPA also issued a Data Evaluation Record or "DER" (i.e., a form used by EPA in its review process to report findings on a study)

for Study Nos. 56 and 62. The compensability of Study Nos. 56 and 62 finds further support in EPA's citation of Study Nos. 56-58, 60 and 62 in its June 5, 2009 report entitled "Preliminary Problem Formulation for the Ecological Risk and Drinking Water Exposure Assessments for Glyphosate and its Salts." Ex. 26, Tabs 56-58, 60 and 62.

We find, therefore, that Study Nos. 48-55, 59, 61 and 63 are not compensable.

With regard to Study Nos. 96-97, we also do not find them to be compensable. These were residue studies regarding new conjugates of AMPA. EPA noted that it reviewed data on April 3, 1998 which included the studies and they received MRIDs. However, as with the earlier AMPA studies, we find that Monsanto did not meet its burden of proof as to compensability. There is no indication that EPA requested or required the studies. We note that, in submitting them, Monsanto said that "... the Agency has said it no longer considers AMPA of toxicological significance ... and we believe that this decision includes the AMPA conjugates." Ritter Ex. 1095, Study 96. We do not find a persuasive evidentiary basis for an inference that EPA would have required Ritter or other applicants to provide this kind of data if Monsanto had not provided it.

vii. Analytical Enforcement Method and Acute Toxicity Studies (Study Nos. 151, 154-166)⁷

Ritter disputed the compensability of Study Nos. 151, 154-157 and 164, as well as the previously discussed Environmental Fate Study No. 106 and Non-Target Organism Study No. 107, since they allegedly concerned products that are not substantially similar to its product. Ritter raises similar arguments concerning other disputed studies, Study Nos. 114, 115 and 117 (previously addressed in Foreign Residue/Import Tolerance category) and Study Nos. 118-122 (previously addressed in Non-

⁷ Although Ritter lists Study No. 151 as a separate category called Analytical Enforcement Method, we will discuss it along with the disputed studies in the remaining category called Acute Toxicity Studies since Ritter's principal objections for both categories are similar.

Target Organism category), since they allegedly concerned uses that were not substantially similar to its product uses.

For the following reasons, we do not agree with Ritter and find all of the disputed studies to be compensable.

Ritter's objections are lodged in its interpretation of language in the cite-all regulation at Section 152.86(d)(2)(ii). Pursuant to that regulation, Ritter acknowledged reliance on all "data in the Agency's files which. . . [i]s one of the types of data that EPA would require to be submitted if the application sought the initial registration under FIFRA section 3(c)(5) of a product with composition and intended uses identical or substantially similar to the applicant's present application." 40 C.F.R. 152.86(d)(2)(ii).

The record confirms that the technical product glyphosate is an acid. However, in order to facilitate shipping, packaging and application of glyphosate, it is formulated into various salt forms, including isopropylamine ("IPA") salt, ethanolamine salt and potassium salt although the most common form is the IPA salt. According to Ritter, since it only has an IPA salt end-use formulation, studies which were conducted using other salt forms are not "substantially similar" to its IPA salt product and, therefore, are not compensable. Ritter Brief at 55-60.

The active ingredient that kills weeds in all glyphosate products is the glyphosate acid. 40 C.F.R. 152.3. Although Ritter has an IPA salt registration for six products, it also has a technical glyphosate registration. We are satisfied from the evidence of record, including testimony from [REDACTED] that, for purposes of registration, EPA treats all of the salt forms of glyphosate the same. See Monsanto Cross Ex. 4; Monsanto Cross Ex. 5, PR Notice 97-5, at 11. Also, Ritter used the "cite-all" method to secure its technical registration for glyphosate. As mentioned, the technical acid product can be used to produce an end-use product in any of the salt forms of glyphosate, not just an IPA salt.

Furthermore, in seeking expedited review of its glyphosate applications, Ritter confirmed to EPA in those applications that each of its glyphosate products was "substantially similar" to particular

Monsanto glyphosate products. See Ex. 417 at MONO88138 (Box 6); Ex. 9 at MONO87166 (Box 6); Ex. 303 at MONO87340 (Box 6). EPA then allowed the expedited review.

There also is evidence, including testimony we find to be persuasive from Ms. McGaughey, that Monsanto generated and submitted data in the disputed studies at least in part to show EPA that data for one salt form of glyphosate can be used to support the registration of other salt forms and of glyphosate generally.

We are quite simply unpersuaded by Ritter's other arguments as to what is or is not "substantially similar," given other compelling evidence of record and basic common sense. Ritter relies on language in EPA's 1992 Blue Book of general information (Ritter Ex. 1026 at 6-11) and a 1996 EPA letter (Ritter Ex. 1045, Tab A). In this regard, we are unable to accept the contention that products are not substantially similar for registration purposes because they may use different hazard signal words. We also do not find it to be persuasive on this point, for example, that EPA's Data Submitters List is organized by active ingredient. Ritter Brief at 55-56.

Finally, for the above reasons, and noting that Ritter has a technical glyphosate registration, we must reject Ritter's position that, for compensability purposes, Monsanto must demonstrate that its data regarding products other than IPA salt products were used because data on IPA salt products data was not available. Ritter Brief at 57-58. In this regard, we note that the panel in BASF Corp. and Albaugh, Inc., No. 23 171 00040 00 (Sept. 25, 2002) heard testimony from Ms. McGaughey on a similar question. Albaugh had objected to studies that tested with certain dicamba salts for which Albaugh did not have a registration because they were patented by BASF. That panel agreed with her testimony that any one of the six [dicamba] salts could be used to support, or bridge to, data for another. Id. at 28-29. We also agree with her testimony on this subject in this proceeding.

Accordingly, the record supports that these studies are compensable even though Ritter argues that Studies 106 and 107 concerned a Monsanto ethanolamine salt of glyphosate; Study 151 concerned

a Monsanto response to an EPA data call-in notice for sodium aciflourfen and concerned product chemistry required in Part 158 for an end-use product; and Study Nos. 154-157 and 164, although they concerned IPA salt products and had hazard warnings different from those used by Ritter. Ritter Brief at 58-60.

Citing the language in Section 152.86(d)(20(ii) that products must also have “intended uses [that are] identical or substantially similar”, Ritter argues that whether or not uses are “identical or substantially similar” can be determined based on a comparison of the directions for use on the parties’ labels. It then claims that Study Nos. 114, 115 and 117-122 are not compensable because they concerned uses not on Ritter’s glyphosate label. Ritter asserts that Study Nos. 114 and 115 address Roundup Ready wheat and Study Nos. 117-122 address Roundup Ready rice, products which are not on its labels (primarily because EPA has not approved the use of glyphosate on these glyphosate-tolerant crops). As we previously found, however, these studies also support the use of glyphosate on conventional wheat and conventional rice, both of which are on Ritter’s labels. Finally, we find that it is not correct, as Ritter claims, that Study No. 114 was withdrawn by Monsanto.

viii. Summary of SOC Exhibit 2 Claims

For all of the above reasons, we have determined that Monsanto has met its burden of proof as to the compensability of the studies in SOC Exhibit 2 except for Study Nos. 48-55, 59, 61, 63, 96 and 97. The amount of the compensation to be owed by Ritter to Monsanto for the proven studies will be determined later herein.

Notwithstanding the foregoing, because Monsanto has not claimed a Base Study Cost or any other cost for Study Nos. 27, 63, 78, 108, 109, 155 and 157, it cannot recover any amount in this proceeding related to those specific studies.

3. SOC Exhibit 3 Claims

a. Nature of the Claim and the “Weediness” Problem

Monsanto seeks to recover \$12,451,000.00 for these claimed data costs before allocation of a portion thereof to Ritter.

SOC Exhibit 3 summarizes, on a crop-by-crop basis, the data which Monsanto allegedly developed to satisfy EPA’s data requirements under FIFRA related to “weediness” for the registration of the use of glyphosate on its glyphosate-tolerant crops. Those crops are: Roundup Ready Soybean 40-3-2, Roundup Ready Cotton 1445, Roundup Ready Corn GA 21, Roundup Ready Canola RT73, Roundup Ready 2 Corn NK603, Roundup Ready Flex Cotton 88913, Roundup Ready Alfalfa, Roundup Ready 2 Corn MON 88017 and Roundup Ready 2 Yield Soybean MON 89788. As discussed, these crops have been genetically modified by inclusion of a gene which enables them to tolerate glyphosate applied to the growing crops, *i.e.*, they are not killed upon such application.

Sometimes called “gene flow”, “weediness” concerns the question of whether the genetic material responsible for herbicide tolerance is either transferred to the weed population or may turn the crop itself into a weed. Said another way, weediness is the ability of a plant to survive, spread seed and propagate despite adverse environmental stressors.

The record confirms that there are two principal ways that herbicide tolerance can be transferred to the weed population. One way is through so-called “volunteers.” A “volunteer” plant is one that, although not planted in a given year, regrows when a different plant has been planted and is supposed to be growing in that year. Such “volunteer” plants are considered to be weeds and are problematic as they compete with the planted crops for water, nutrients and sunlight. (As a general proposition, weeds compete for light, water and nutrients with emerging plants with a resulting immediate impact on overall crop yield.)

The other way for herbicide tolerance to be transferred is through so-called "cross-breeding." Crops can also cross-breed with sexually compatible weedy "relatives" to generate new weeds. If the herbicide tolerance in the herbicide tolerant crop were transferred to the weed population through either of these means, the herbicide could no longer control the weed. This would mean that farmers would need to turn to other ways to control weeds, such as using different or larger amounts of toxic pesticides or increasing "tillage" of their fields.

Dr. [REDACTED] Monsanto's former Senior Regulatory Advisor, Regulatory Affairs and Policy, provided important testimony at the hearing regarding both the "weediness" claims (SOC Exhibit 3) and "weed resistance" claims (SOC Exhibit 4). His testimony was particularly helpful given his educational background in agronomy (i.e., field crop production and soil management) and his various work experiences with Monsanto. These included about 20 years (from 1992 until his retirement in 2012) as Monsanto's "regulatory lead" in Washington, D.C. whereby he interacted with the relevant federal agencies, primarily EPA, on a "regular basis" and was "responsible for all of Monsanto's interactions with EPA, FDA, and USDA on agricultural chemistries and products of biotechnology." See

Direct Testimony at para. 13.

According to Dr. [REDACTED] he developed strong working relationships with the various agencies during his Washington, D.C. tenure. Dr. [REDACTED] was in charge of the registration with EPA of all of Monsanto's agricultural herbicides. It was his "job to ensure that all of Monsanto's herbicides, both registered and experimental, as well as [its] biotechnology derived products, met the regulatory requirements of all of the agencies." Id. Dr. [REDACTED] reviewed documents which were submitted to the various agencies "to ensure that Monsanto was meeting the regulatory requirements, including data requirements, in order to move a product through the regulatory process toward regulatory approval and commercialization." Id. He also served as Monsanto's liaison between its corporate offices in St.

Louis, Missouri and the regulators in Washington “so that all questions and concerns of the agencies were properly and adequately addressed.” Id.

Dr. explained that “tillage” may include plowing the soil and generally involves manipulating the soil by mechanical means in preparation for planting or for weed control. As a result of tillage, weed roots are either cut or the entire weed may be buried. Although tillage cuts the root system from the growing plant or buries weeds, it also disturbs the topsoil and makes the nutrient-rich topsoil vulnerable to both wind and water erosion. Once the soil is displaced, it is no longer available to nourish seed being grown. It also, however, can contaminate streams and groundwater with the residue from pesticides, nitrogen and other fertilizer compounds that may be present in the soil.

As also explained by Dr. “cultural” practices are techniques and procedures which growers implement in agricultural production systems and are designed to maximize yield and crop health. These practices include, e.g., crop rotation, planting techniques, and also tillage.

So-called “reduced tillage” or “no till” farming is a cultural practice designed to avoid the kind of “drawbacks” of tillage while also allowing a grower to maintain weed control. “No-till” farming is the planting of a crop without disturbing the soil surface or the residue on the soil surface. This is typically accomplished by applying herbicides to eliminate surface weeds before seed are planted. According to Dr. glyphosate was instrumental in the adoption of reduced tillage and “no till” farming well before glyphosate-tolerant crops were introduced. This was because of glyphosate’s “human and environmental safety profile and its broad spectrum ability to kill all types of weeds. . . .” Id. at para. 69. Through “reduced tillage”, the soil is minimally disturbed in preparing the seedbed for seed planting. Through “no-till” farming, a farmer is able to kill weeds and plant directly into the residue from the previous crop without disturbing the soil. This can actually increase moisture available to the seeds and reduce or eliminate soil erosion.

Dr. testified that EPA has been very supportive of “reduced tillage” and “no-till” farming because these cultural practices reduce soil erosion caused by wind and water. He further testified, based on his personal conversations with the EPA employees with whom he dealt, that EPA was a “very big proponent of reduced tillage and no-till farming.” Id. His testimony, which was supported by other Monsanto witnesses, is important to our consideration of this claim and is uncontroverted. As discussed below, EPA had significant concerns regarding weediness, and the potential that use of glyphosate on Monsanto’s glyphosate-tolerant plants would create unreasonable adverse environmental effects of the kinds described above.

b. EPA’s Requirement for Weediness Data and Role of APHIS

On May 24, 1995, Monsanto secured its initial approval from EPA for the new use of glyphosate on a glyphosate-tolerant crop, soybeans. This approval came through a letter from EPA’s Robert Taylor. Ritter does not dispute certain facts concerning that letter: Consistent with the provisions of Sections 152.115(c) and (d) of the regulations, EPA therein imposed data requirements on Monsanto as a condition of the registration for the use of glyphosate on glyphosate-tolerant soybeans. According to the letter, “the amendment referred to above, submitted in connection with registration under FIFRA sec. 3(c)(7)(A), is acceptable provided that you:

1. Submit data or information to address the following concerns:
 - A. Whether or not this registration will increase the use of herbicides.
 - B. Whether or not this registration will affect presently use [sic] cultural practices (e.g., reduced tillage, no till).
 - C. Whether or not the genetic material responsible for herbicide tolerance in the crop is transferred to the weed population.

* * * * *

If these conditions are not complied with, the registration will be subject to cancellation in accordance with FIFRA sec. 6(e)."

We have examined these conditions in the light of the record evidence. The first condition imposed by EPA related to EPA's concern that, although glyphosate is an herbicide with a very favorable environmental and safety profile, its increased use could become so great that it would lead to so-called "weed resistance" to glyphosate in the weed population. This, in turn, could lead to the use of more toxic pesticides in place of glyphosate. EPA wanted to ensure that this possibility did not occur. Hence, it requested data on the overall use of herbicides.

The second condition also relates to "weed resistance." It addresses EPA's concerns that the use of glyphosate on glyphosate-tolerant soybeans could impact the reduced tillage and "no-till" cultural farming practices as to which EPA was such a strong proponent. EPA wanted to see the use of these environmentally critical practices continue and expand. It was concerned that this would not happen if weeds developed resistance to glyphosate, making them unable to control the weeds. This would lead growers either to use more toxic pesticides to accomplish "no-till" or reduced tillage farming or to incorporate more aggressive tillage. As discussed, reduction in the favorable reduced tillage and "no-till" cultural practices would produce an adverse effect on the environment. For instance, it could lead to wind or water erosion, increased environmental contamination of lakes, streams and groundwater and/or the use of more toxic herbicides.

We will discuss Monsanto's claim for compensation based on "weed resistance" data in the next section of the Award.

The third condition of registration imposed by EPA addressed its "weediness" concerns with regard to the environmental effects which could result from using glyphosate on glyphosate-tolerant soybeans. As indicated, Ritter's application used the "cite-all" method. Sec. 152.86 expressly defines

required "pertinent data" for purposes of such an application to include data which "concerns the . . . effects of the applicant's product . . ."

This third condition expressed EPA's concern that, if herbicide tolerance was transferred from the glyphosate-tolerant crop to the weed population, glyphosate could no longer control the weeds. As a result, weeds would have to be controlled through different methods. These could include ones which could produce the kind of environmental effects that EPA viewed as posing an adverse effect on the environment, such as use of more toxic pesticides, increased tillage and hand labor.

Dr. [REDACTED] had numerous meetings and conversations with EPA regarding the data requirements imposed in its conditional approval for the use of glyphosate on glyphosate-tolerant soybeans. Thereby, he gained a better understanding of the kind of data required to satisfy EPA's conditional registration. Specifically, Monsanto understood that EPA wanted data, not just on weediness but also on weed resistance. Further, it wanted data on both short-term impacts and long-term environmental effects previously described.

Ritter does not dispute that EPA imposed weediness and weed resistance data requirements on Monsanto as a condition for registration of the use of glyphosate on glyphosate-tolerant soybeans. Ritter also does not dispute that EPA then again imposed these requirements including in 1999 as a condition for registration of the use of glyphosate on glyphosate-tolerant canola. Ritter Brief at 28-29. It is the Panel's conclusion, based on the evidence of record and the reasonable inferences we have drawn from that evidence, including Dr. [REDACTED] personal dealings with EPA, that EPA imposed "weediness" data requirements as to all of Monsanto's Roundup Ready crops included in SOC Exhibit 3.

Doing so is in full accord with EPA's powers and responsibilities under FIFRA and applicable EPA regulations to require such data. In addition to its authority to impose additional requirements through conditions of registration, EPA has wide latitude under the "flexibility" provisions of 40 C.F.R. 158.30 to require this kind of data. Indeed, referencing "traditional" Part 158 guidelines, EPA expressly reminded

applicants that it could “require the submission of additional data or information beyond that specified in this part if such data or information are needed to appropriately evaluate a pesticide product.” 40 C.F.R. 158.30(b). Ritter itself recognizes: “The scope of Part 158 is to describe the ‘minimum data and information EPA typically requires to support an application for pesticide registration.’” Ritter Brief at 26 (citing Sec. 158.1(b)). As also discussed below, Monsanto was seeking a novel and unprecedented use for glyphosate on a genetically modified crop. It is not surprising in such circumstances that EPA would have required that the additional data be provided to it given the concerns reflected in its conditional approval.

To comply with EPA’s requirements, Monsanto submitted a report on March 19, 1996 by the Sparks Company regarding the impact of the introduction of its Roundup Ready soybeans. It also submitted its petition for “non-regulated” status of Roundup Ready soybeans which it had submitted to the Animal and Plant Health Inspection Service (“APHIS”) within the U.S. Department of Agriculture (“USDA”). Therein, it sought APHIS’s approval to market and sell Monsanto’s glyphosate-tolerant seed for soybeans. Said another way, it had asked APHIS to remove its glyphosate-tolerant seed from APHIS regulation, *i.e.*, to “deregulate” it. Ritter concedes that in its decision to deregulate glyphosate-tolerant soybeans, APHIS addressed weediness and weed resistance. Ritter Brief at 28.

APHIS is one of the three U.S. agencies, along with the FDA and EPA, which is responsible for regulating agricultural biotechnology. Pursuant to its statutory authority under the Plant Protection Act, 7 U.S.C. 7701 *et seq.*, APHIS looks specifically at potential plant pest risks which a genetically engineered organism might pose. FDA, pursuant to its statutory authority, generally is responsible for reviewing the safety of food and animal feed products that are derived from genetically engineered crops. Finally, EPA pursuant to FIFRA regulates the use of pesticides on or in the crops, *e.g.*, the use of glyphosate on glyphosate-tolerant crops.

The record indicates that a petition for non-regulated status submitted to APHIS had to include information regarding the weediness of the genetically engineered plant and the potential impact that the genetically engineered plant might have on the weediness of any related plant with which it might cross-breed. 7 C.F.R. 340.6(c)(4). This was required pursuant to APHIS's mandate to ensure that the Roundup Ready crop under review was not a plant pest under the Plant Protection Act.

We find, based on the evidence, that the type of information and data as to weediness which Monsanto was required to submit to APHIS in seeking approval of the Roundup Ready crops was the same type of information and data that Monsanto was required to submit to EPA in seeking its approval to use glyphosate on those crops. This information and data also was the same type of information and data that EPA, on May 24, 1995, specifically required Monsanto to provide to EPA pursuant to EPA's conditional approval for the use of glyphosate on Roundup Ready soybeans and, as the record shows, that EPA also required for the other glyphosate-tolerant crops included in SOC Exhibit 3.

Accordingly, we find that the data and information that Monsanto had to develop as to "weediness" to support each petition for de-regulated status of the genetically modified plant was essentially the same information that Monsanto was required to provide to EPA to support the new use of glyphosate on each of the glyphosate-tolerant plants.

Each petition for non-regulated status to APHIS contains a sworn statement affirming that the petition accurately reflects all of the data collected by the applicant. Monsanto maintains the raw data and study reports upon which each petition is based. Thereby, regulators can, if they choose, inspect the data and reports to ensure that the summary of the data presented in the petition is accurate. APHIS does not require study reports underlying the petition summary to be formatted in a particular way. However, knowing that these data also must meet EPA data requirements, Monsanto formats such reports consistently with EPA study formatting requirements.

It is not surprising that since there are several federal agencies responsible for agricultural biotechnology matters, the U.S. Government has a formal agency coordination policy in place. Called the "Coordinated Framework," it was established in 1986 and generally outlines how the technology would be regulated by the federal government. It recognized that the agencies had an obligation to share data and coordinate reviews of biotechnology products. The Coordinated Framework was published by the Office of Science and Technology Policy and is titled "Coordinated Framework for Regulation of Biotechnology." See 51 Fed. Reg. 23302 (June 26, 1986). We understand from the evidence presented to us that, although each of the involved agencies would operate under its own independent statutory authority, they would share data and coordinate reviews when the agencies' different statutory obligations required them to review the same data.

The record indicates that, by the late 1990's, EPA took the position that it would not approve the use of glyphosate on a Roundup Ready crop unless and until that crop had been deregulated by APHIS. Clearly, this was a sensible approach simply based on the fact that the new use depended entirely on whether the plant on which the new use would be made was allowed by APHIS to be marketed, sold and planted.

A Memorandum of Understanding, dated February 23, 2001, between EPA's Office of Pesticide Programs and APHIS (the "MOU"), served to underscore in a more formal way the importance of the ongoing, and necessary, coordination which had taken place between the two agencies as part of the Coordinated Framework regarding biotechnology issues of common interest. These issues included both weediness and weed resistance. In this regard, the MOU referenced, among the "specific coordination measures that can be implemented," that "APHIS will provide EPA a copy of APHIS petitions for non-regulated status for herbicide-tolerant crops." Ex. 82. Based upon this requirement, the Coordinated Framework, the testimony of Dr. [REDACTED] who had direct dealings with EPA on an

ongoing basis, and other evidence of record, it is apparent that APHIS and EPA coordinated their efforts and shared information of mutual interest including as to weediness and weed resistance.

Indeed, the MOU specifically addressed the agency's common concerns as to weediness and weed resistance:

APHIS will ask each petitioner of herbicide-tolerant crops to submit a voluntary stewardship plan for the management of pest resistance and potentially weedy volunteer crops in their herbicide-tolerant crops and crop rotations. Since APHIS receives petitions from registrants of herbicide-tolerant crops far in advance of EPA's receiving an application for registration of the herbicide on that crop, APHIS will consult with EPA as to the viability of the stewardship plans while preparing the APHIS EA [environmental assessment]. Having the two agencies concur on a stewardship plan early on in the registration process will ensure that the concerns of both agencies are addressed, and that these concerns are discussed in the EA along with the details of the plan and its implementation. The opportunity for the public to comment on both the petition and EA ensures transparency in the joint review process. Id.

We also find that the "voluntary stewardship plan" referenced by the MOU was voluntary for the grower, but not for the registrant. Thus, Monsanto was required to develop and submit such a plan, and it did so. We also find that the stewardship plan was required by EPA in order to satisfy the data requirements included in the conditions of registration for the approval of the use of glyphosate on Roundup Ready soybeans as well as to satisfy the data requirements included in the conditions of registration for the approval of the use of glyphosate on the other Roundup Ready crops included in SOC Exhibit 3. These are described above at Section III. B.

As indicated, the record establishes that EPA required "weediness" data not just for Roundup Ready soybeans, i.e., Roundup Ready Soybean 40-3-2 and Roundup Ready 2 Yield Soybean MON89788, but also for the other Roundup Ready crops included in SOC Exhibit 3. As for Roundup Ready Cotton 1445 and Roundup Ready Flex Cotton 88913, in its letter dated October 23, 1996, EPA indicated that the "weediness" information relative to its concerns regarding transfer of the glyphosate tolerant gene as to soybeans to the weed population "is also required for cotton with the Roundup Ready Gene. . . ." Ex.

61. As for Roundup Ready Corn GA21, Roundup Ready Corn 2 Corn NK603 and Roundup Ready 2 Corn MON88017, EPA indicated in its October 23, 1996 letter that the information "... will also apply to corn with the Roundup Ready Gene, once that use is registered." Ex. 61. With regard to Roundup Ready Canola RT73, again expressing such concerns, in its March 31, 1999 letter, EPA required Monsanto to "[s]ubmit data to demonstrate that the gene will not move into other plants." Ex. 76.

Although the record does not include a letter in which EPA also required "weediness" data for Roundup Ready Alfalfa, we are satisfied from the record as a whole, including the testimony of Dr.

and Mr. Tinsworth, and the reasonable inferences we have drawn from all of the evidence, that EPA's "weediness" requirement also included Roundup Ready Alfalfa. There is evidence of record that, as recently as January, 2011, EPA had significant "weediness" concerns regarding the use of glyphosate on Roundup Ready Alfalfa.

We are satisfied from the evidence presented, and through reasonable inferences which we have drawn from that evidence, and consistent with EPA's conditional approvals for glyphosate to be used on these crops, that first, EPA's "weediness" concerns as to all of the Roundup Ready crops has continued to the present; and second, that EPA's requirement for "weediness" data also has continued to the present. This evidence includes the following: the MOU's requirement for APHIS to provide EPA with petitions for non-regulated status (including summaries of "weediness" data); EPA's withholding registration approval in 2002 for use of glyphosate on glyphosate-tolerant wheat and bentgrass because of "weediness" and weed resistance issues (67 Fed. Reg. at 60934); the January 25, 2011 EPA document which expressed concerns about "gene flow" as it related to glyphosate-tolerant alfalfa; a July 12, 2012 EPA/USDA joint statement which addressed genetically-engineered crops and the use of herbicides on those crops and in which the agencies committed to continuing to work together to ensure that the "best available information is used, that our agencies [will] thoroughly and carefully consider the potential human health, plant health, environmental and other relevant impacts, and that our agencies

reach conclusions that are consistent with and fulfill our respective responsibilities and statutory mandates" (Ex. 438); and, a "joint review process" which is ongoing between EPA and APHIS related to "weediness" and other mutual concerns.

Significantly, there is nothing in the record which suggests that EPA's requirement for "weediness" data at any time ended, or that it has been waived by EPA. In this regard, EPA regulations have a formal procedure for data requirements to be waived. This procedure requires that all waiver requests be made in writing. 40 C.F.R. 158.45(b)(2). No such written request, or any other evidence that EPA has withdrawn its data requirement, is included in the record.

Although Ritter argues that there was no EPA requirement for "weediness" data on February 9, 2005 when it secured its initial glyphosate registration (Ritter Brief at 28-32), the record clearly is to the contrary. Ritter argues that there was no requirement because "weediness" and weed resistance were not Part 158 core guidelines and because there is no reference to the data in EPA's 2009 plans to reconsider the registration of glyphosate. However, these arguments are reed thin when compared to the substantial body of evidence which supports EPA's requirement. We also do not find it remarkable from a regulatory perspective that there has been no formal agency action with Monsanto regarding the "weediness" data requirement since March 31, 1999 when EPA conditionally approved the use of glyphosate on Roundup Ready Canola. Ritter argues that this is evidence that the requirement did not exist after 1999, and thus did not exist in February, 2005 when it received its initial glyphosate registration (Ritter Brief at 24). However, we view this rather as evidence that EPA has been satisfied with the data and information which Monsanto has provided although the requirement continues.

We also are not persuaded by Ritter's argument that the data were not required because EPA granted registrations to other follow-on "selective" method glyphosate applicants that did not cite to weediness (or weed resistance) data in their applications. The evidence of record does not support Ritter's position with regard to the application since the data matrix on which EPA based that

registration was prepared after Monsanto and [REDACTED] had settled their data compensation dispute. Further, since the matrix included notations which indicated that a settlement had occurred, we find that EPA would have understood that a thorough review of the matrix was not needed.

Although [REDACTED] testified that [REDACTED] had prepared a number of EPA-approved glyphosate applications for other follow-on applicants that did not cite to "weediness" (or weed resistance) data, the record does not include any of these allegedly "selective" method applications. Even if it did, however, from our consideration in this arbitration proceeding of the record on the Motion to Strike, we are aware that these follow-ons generally used the previously discussed "cite-all option" under the "selective" method to satisfy certain data requirements. As a result, since they also submitted general offers to pay and Certifications to EPA, and as the record otherwise indicates, it does not appear, first, that EPA would have been especially concerned about the completeness of their data matrices; and second, that EPA ever conducted a comprehensive review of any of the follow-on applicants' data matrices prepared by [REDACTED].

C. The Weediness Data Was Submitted To, Considered and Relied Upon by EPA

As mentioned above, Monsanto's petition for deregulation, containing a summary of the "weediness" data it generated for Roundup Ready Soybean 40-3.2, was submitted directly to EPA. Monsanto also submitted to EPA its similar petition for Roundup Ready Canola, which also received an MRID. For Roundup Ready Cotton 1445, Monsanto submitted to EPA the determination by APHIS of non-regulated status. This included a determination that the crop was unlikely to present "weediness" concerns. Monsanto also submitted to EPA APHIS's determinations of nonregulated status, which contained APHIS's determination of "weediness" potential, for Roundup Ready Soybean 40-3-2 and Roundup Ready Canola RT73.

On the basis of (a) the testimony of Dr. [REDACTED] (b) the Coordinated Framework, (c) the MOU's requirement that APHIS share deregulation petitions with EPA, (d) the obvious need for APHIS and EPA to share data and information essential to both agencies in fulfilling their separate statutory responsibilities and (e) other inferences we reasonably draw from the evidence, we find that the "weediness" data concerning the Roundup Ready crops which were submitted by Monsanto to APHIS were shared by APHIS with EPA. In this regard, according to Dr. [REDACTED] the two agencies shared data and coordinated the review of Monsanto's weediness data summaries. Also, Dr. [REDACTED] understood, based on his direct dealings with EPA, that copies of Monsanto's deregulation petitions to APHIS were provided by APHIS to EPA both before and after the MOU was finalized. His testimony was not controverted.

Nonetheless, for purposes of Section 152.86(d) and Ritter's cite-all method application under that regulation, Ritter maintains that none of the SOC Exhibit 3 data can be considered to have been "in the Agency's files." Ritter Brief at 21-24. We disagree for the above reasons. Moreover, both Ms. McGaughey and Mr. Tinsworth testified that not all compensable data are physically submitted to EPA, but they are considered to be "in the Agency's files" for purposes of Section 152.86(d). We found their testimony to be persuasive. In this digital age, when hard copies of documents in physical files are becoming more and more the exception rather than the rule, we believe it is reasonable to view what is "in the Agency's files" to include electronic documents, as well as information such as the Monsanto deregulation petitions that is available to the Agency for its consideration through accessible web-based databases such as the APHIS website. Moreover, the underlying raw data supporting the petitions were available to EPA from Monsanto in the event EPA wanted to review it.

Our conclusion is not changed by [REDACTED] testimony that [REDACTED] could not secure from EPA, through an August 5, 2011 Freedom of Information Act request, a copy of one of Monsanto's deregulation petitions to APHIS. This fact is not persuasive given that the request did not mention

glyphosate and it may not have been directed to all appropriate parties. Moreover, EPA in any event would have had electronic access to the petition. We conclude that we should take this aspect of current information technology into account in assessing the significance of [redacted] experience with this FOIA request.

We also are not persuaded by Ritter's argument that the Exhibit 3 data are not in EPA's files because Monsanto chose not to employ its option to submit each APHIS petition directly to EPA through its "front end" process and secure MRIDs for the petitions. Ritter Brief at 22; Ritter Reply at 20-11. Although Monsanto apparently could have done this, it is our conclusion, for all of the reasons we have discussed, that this clearly was neither necessary nor required. In these circumstances, Ritter's assertion that Monsanto did not format the petitions in the manner provided at Section 158.32 is unpersuasive. That provision was not applicable to this kind of data. On the other hand, the record indicates that, since APHIS did not require study reports underlying a petition summary to be formatted in a particular way, Monsanto, knowing that these data also had to meet EPA requirements, formatted its underlying study reports in a manner consistent with EPA requirements for study formatting.

Further, we have considered Ritter's argument that the data were not required because EPA did not employ its "Data Call-In" procedures to secure the data. Ritter Reply at 10. We find this unpersuasive given that EPA expressly conditioned the subject registrations upon provision of "weediness" and weed resistance data by Monsanto.

Our finding that the data were "in the Agency's files" is also supported by the fact that EPA provided several sets of comments on "weediness" issues related to glyphosate. See, e.g., Exs. 61, 92, 438 and 67 Fed. Reg. at 60,939.

The record supports not only our finding that the "weediness" data were in EPA's files, but also our further finding that EPA reviewed and considered the "weediness" data. First, it is undisputed that EPA required that the data be submitted as a condition for allowing the use of glyphosate on the

glyphosate-tolerant crops. Second, the registrations, although conditional, were not cancelled by EPA even though EPA could have cancelled any of them pursuant to FIFRA Section 6(e) and even reminded Monsanto when it approved the initial application for soybeans that it had that right. Third, the data, although required by EPA, also were required by APHIS and thus had to be developed so that both agencies could fulfill their statutory responsibilities. Fourth, the data which were relevant to each of the Roundup Ready crops were described by Monsanto in its petitions to APHIS. Fifth, pursuant to the Coordinated Framework, and as required by the MOU, both agencies shared data concerning herbicide-tolerant crops and the use of herbicides on them. Sixth, the petitions, which APHIS was required to share with EPA, contained summaries of the data and both agencies were aware that all supporting data were with Monsanto and available to them. Finally, we have noted above the great importance to EPA of the weediness issue. These conclusions are amply supported by EPA documents in the record, and by reasonable inferences we have drawn from those documents, as well as by opinions provided by Mr. Tinsworth at the hearing which we find useful in our analysis.

The development of glyphosate, and the development of glyphosate-tolerant crops, have raised some of the most significant environmental issues of our time. They are at the forefront of public environmental concerns even as this Award is being prepared. Both EPA and APHIS are statutorily charged with the power and responsibility to deal with those concerns. Monsanto's testimony here clearly states that EPA is independently exercising its FIFRA authority when it grants and maintains a registration for the use of glyphosate on a glyphosate-tolerant crop. Similarly, when APHIS deregulates a glyphosate-tolerant seed, it is independently exercising its regulatory authority and responsibility. The record shows that EPA maintains its own independent authority and responsibility under the Coordinated Framework. There is no support here for a finding that EPA defers to APHIS regarding use of glyphosate on crops grown with these seeds. Indeed, Ritter does not argue that EPA has delegated any of this responsibility to APHIS. Thus, within the framework presented in this record, and given the

extensive evidence discussed above concerning EPA's weediness concerns, the Panel majority⁸ finds no basis on which to conclude that the Exhibit 3 studies were not an EPA data requirement under FIFRA. We will treat them as compensable.⁹

d. Summary of Exhibit 3 Claims

For all of the above reasons, we have determined that Monsanto has met its burden of proof as to the compensability of the studies in SOC Exhibit 3. The amount of the compensation to be owed by Ritter to Monsanto for the studies will be determined later herein.

4. SOC Exhibit 4 Claims

a. Nature of the Claim

Monsanto seeks to recover the amount of \$15,095,482.00 for these claimed data costs before allocation of a portion thereof to Ritter.

SOC Exhibit No. 4 summarizes Monsanto's internal, and also external, costs from 1995 through 2010 attributed to studies concerning weed resistance and also concerning label development, including directions for use. The first page is a summary of the costs claimed with five columns: "Year", "Total Internal Study Costs", "Total Internal Management and Implementation Costs", "External Study Costs" and "Total Internal and External Costs."

SOC Exhibit 4 also includes, for each of the claim period years, a 1-page summary which describes the costs claimed. For all of the years, specific cost information is included regarding each of

⁸ The Panel is not unanimous on this issue. One of its members does not agree that "weediness" data is compensable because, among other reasons, the studies and data supporting "weediness" deal with the crop alone and not the effect of glyphosate on the crop and are outside of the scope of Section 152.86(d)(1) notwithstanding EPA's requirement.

⁹ The Panel is aware that this conclusion diverges from the result reached on this issue by the panel in Monsanto Company and Tacoma Ag, LLC, No. 16 171 Y 00228 10 (Mar. 1, 2012). The Panel majority here does not believe that the outcome on this issue in this Arbitration is contradictory of the Tacoma panel's view. Here the record is uncontroverted that EPA independently exercises its statutory authority with regard to the use of glyphosate on glyphosate-tolerant crops. The panel in Tacoma was presented with a very different record. In reaching its result on "weediness", it expressly relied on a finding that EPA deferred to APHIS on "weediness". See Tacoma at 22-26. There is no basis in the record before us for such a finding.

the studies. There are columns that specify the study number, title, whether or not it concerned weed resistance or directions for use (or both), the number of sites, man days per site, total man days, total man years, FTE cost, internal study costs, number of external sites, external study costs and total internal and external study costs. The cost figures also are totaled.

Some of the SOC Exhibit 4 yearly data summaries also include cost information, labeled "Additional Studies", regarding additional weed resistance studies which were performed for Monsanto primarily by universities. There are columns which identify the study number, title and Monsanto's cost for the study. The cost figures also are totaled.

For the years beginning with 2005, the yearly summaries includes cost information, labeled "Management and Implementation", regarding the estimated time of certain Monsanto employees to assist in the management of the weed resistance work and implementation of the directions for use. There are columns which identify the particular group/cost center within Monsanto involved, the individual, whether for weed resistance management or directions for use, total man years, FTE cost and the total internal cost. The cost figures also are totaled.

This claim addresses both weed resistance and directions for use. Ritter opposes compensability for each of them. Our discussion below will separately address each of them.

b. Weed Resistance Data Claim

(i.) The Weed Resistance Problem

Weed resistance in agriculture has been an issue for research and discussion among weed scientists since at least the 1960's. Weed resistance is the ability of a weed to tolerate or withstand a pesticide application which normally would have killed the weed species. Weed resistance is not unique to glyphosate and is an issue for all herbicides. It generally originates with a weed possessing a natural genetic mutation that allows it to survive an herbicide that should kill it. Weed resistance becomes a problem for growers as a result of selective pressure. Selective pressure is similar to the concept of

natural selection. Natural or breeder-directed forces that favor successful reproduction of naturally resistant individuals or genotypes can lead to a change of the genetic composition of a weed population over multiple generations. If an herbicide controls only the weakest weeds in a population, then the survivors reproduce and their offspring will continue to survive with the trait of resistance.

Through his interactions with EPA, and through actions EPA has taken regarding weed resistance, Dr. [REDACTED] was aware that this was a matter of concern to the Agency. He testified that before EPA approves a pesticide for use, the Agency has spent significant time and effort to determine that the pesticide is safe. According to Dr. [REDACTED] "Ensuring that weed resistance to safe pesticides like Glyphosate does not develop, or does not develop rapidly, thus is an important part of EPA's statutory mandate to reduce the risks to humans and the environment from the use of pesticides."

Direct Testimony at para. 57. His testimony was not controverted.

The amount of a pesticide that is used to control weeds can be a factor that contributes to weed resistance. As previously mentioned, EPA's approval of the use of glyphosate on glyphosate-tolerant crops markedly increased the use of glyphosate. Growers proactively can manage the development of weed resistance if they use a combination of different herbicides that have different ways to kill or control a pest. Also, cultural practices, such as mechanical tillage, cultivation and hand weeding or other labor can affect the ability of a weed to survive. Growers undertake these kinds of activities and they can be recommended to them through directions for use (discussed below) on pesticide labels. Since enforcement of these kinds of recommendations can be difficult, stewardship by pesticide manufacturers can be an important part of managing weed resistance.¹⁰

As a result of the introduction by Monsanto of its glyphosate-tolerant crops, Dr. [REDACTED] discussed issues regarding weed resistance with EPA. EPA officials expressed concern that weed

¹⁰ As discussed herein, EPA required Monsanto to develop stewardship plans regarding weed resistance management.

resistance to glyphosate would develop as a result of the increased use of glyphosate on these crops. According to Dr. [REDACTED] EPA did not want weed resistance issues to impact the widespread, safe use of glyphosate in agriculture or around homes and gardens. Weed resistance to glyphosate could lead to the use of other pesticides that did not have a safety profile as strong as the one for glyphosate. Through his conversations with EPA, it became apparent to Dr. [REDACTED] that EPA was interested not only in the short-term impacts of the new use of glyphosate on glyphosate-tolerant crops. It also was worried about long-term environmental effects that could result from this new use. This included whether the new use would somehow create new weeds that glyphosate could not control, and what the impacts of that might be, such as more herbicide use or use of more toxic herbicides or the increased use of tillage. As discussed, EPA was a strong proponent of "no-till" or reduced tillage cultural practices.

It is not surprising, therefore, that EPA conditioned Monsanto's registrations for the new use of glyphosate on its Roundup Ready crops on the requirement that Monsanto provide data and information on weed resistance.

As also recognized by Ritter: "EPA can . . . issue a 'conditional registration' that allows registration but subjects the registration to possible cancellation if certain conditions are not met. . . ." (citations omitted). Ritter Brief at 27.

(ii.) EPA's Requirement for Weed Resistance Data

As discussed above, on May 24, 1995, Monsanto secured its initial new use registration for glyphosate on its Roundup Ready crops. We have already discussed the condition to that registration for Roundup Ready soybeans, regarding required "weediness" data, with the threat of potential cancellation if not fulfilled. EPA also conditioned the registration on Monsanto providing required weed resistance data. Specifically, EPA required Monsanto to "[s]ubmit data or information to address the following concerns:

- "A. Whether or not this registration will increase the use of herbicides.
B. Whether or not this registration will affect presently use [sic] cultural practices (e.g., reduced tillage, no till)." Ex. 57.

EPA also stated: "If these conditions are not complied with, the registration will be subject to cancellation in accordance with FIFRA sec. 6(e)." Id.

In our earlier discussion of the May 24, 1995 document, we explained the nature of these concerns in detail and the potential adverse effects related to those concerns. As discussed, EPA feared that if the new use of glyphosate led to weed resistance, growers could address this problem through the use of other and more toxic pesticides and resort to increased tillage and other unfavorable cultural practices. This, in turn, would lead to wind or water erosion and the increased environmental contamination of lakes, streams and groundwater.

In addition to the May 24, 1995 letter, these weed resistance data requirements were stated by EPA in other correspondence with Monsanto. In its October 23, 1996 conditional approval letter, EPA stated: "Please note this information is also required for cotton with the Roundup Ready Gene and will also apply to corn with the Roundup Ready Gene . . ." Ex. 61. Also, with regard to Roundup Ready corn, a March 28, 1997 letter from EPA to Monsanto reiterated the requirement that Monsanto submit information to address whether or not the registration "will increase the use of herbicides" and "will affect presently used cultural practices such as no till." Ex. 72.

The record, including testimony from Mr. Tinsworth, indicates that EPA also required the data for canola. In EPA's March 31, 1999 letter to Monsanto conditionally approving the use of glyphosate on Roundup Ready canola and on sugar beets (not included in Monsanto's claim), EPA required Monsanto to "[s]ubmit data to demonstrate that the amount of pesticide used does not increase as a result of the use on canola . . . with the Roundup Ready Gene." EPA required Monsanto also to "[s]ubmit data to demonstrate whether the uses will have an effect on agricultural use practices, i.e., reduced tillage and no-till practices." Ex. 76. According to Dr. [redacted] based on his direct dealings with EPA, he

understood that the weed resistance data were required for EPA's approval of the use of glyphosate on every Roundup Ready crop. Based upon the evidence of record, and the reasonable inferences we have drawn from that evidence, we find that EPA imposed weed resistance data requirements as to all of Monsanto's Roundup Ready crops included in SOC Exhibit 4.

As we have mentioned, it was also apparent to Dr. [REDACTED] through his dealings with EPA that the Agency was not only interested in the short-term impacts of the new use of glyphosate but was also concerned about the long-term environmental effects. EPA worried whether this new use would somehow create new weeds that glyphosate could not control, and what the impacts on greater herbicide use or increased tillage would then be. In other words, EPA's data requirement extended not only to weediness but also to weed resistance. Once again, Dr. [REDACTED] testimony was not controverted.

Ritter concedes that APHIS addressed both weediness and weed resistance in its initial decision deregulating soybeans. Ritter also recognizes that EPA's new use approval was conditioned on the provision of additional data. Ritter Brief at 28. Ritter asserts, however, that the data requirement no longer existed at the time it secured its initial glyphosate registration in February, 2005. It argues, as it also did regarding the weediness data, that the requirement had ended because there was no formal "Regulatory Action" by EPA after March 31, 1999, when Monsanto secured its conditional registration for canola. Ritter relies on a Monsanto demonstrative exhibit in support. In our "weediness" discussion, we previously addressed, and rejected, this argument. We also reject it here. We also reject Ritter's argument that no requirement existed in 2005 because EPA approved an unconditional registration in 2010 for [REDACTED] for its own glyphosate-tolerant crop and EPA did not mention weed resistance or weediness. Ritter Brief at 30. As Monsanto notes, however, that registration was for an end-use product, not a technical registration adding a new use. Also, the registration does not indicate what data [REDACTED] may have been required to submit regarding weediness and weed resistance before the

registration was issued. Monsanto Reply at 6. For these and other reasons, we do not find Ritter's argument to be persuasive.

As indicated, the MOU required each petitioner addressing herbicide-tolerant crops to submit a "voluntary stewardship plan for the management of pest resistance and potentially weedy volunteer crops in their herbicide-tolerant crops and crop rotations." Ex. 82. Although "voluntary" for growers relative to their compliance with the plans, development and submission of these plans was required, both by APHIS and by EPA, for manufacturers such as Monsanto. EPA's requirement as to Monsanto stemmed from its conditional approvals of the use of glyphosate on Monsanto's Roundup Ready crops. Monsanto developed and submitted its weed resistance stewardship plans initially to APHIS as part of its petitions for deregulated status. These plans were then made available to EPA either when directly submitted by Monsanto to EPA or through the required provision by APHIS of the petitions to EPA as discussed above. For all of these reasons, and from reasonable inferences we have drawn from the evidence of record, we find that EPA required the weed resistance stewardship plans.

Ritter's remaining arguments here with regard to the requirement for weed resistance data are essentially the same arguments it made with regard to the requirement for "weediness" data. We have rejected those arguments above and explained why. We also reject those arguments here. We see no need, however, to address those arguments again here. Suffice it to say that for reasons already discussed, EPA's requirement for weed resistance data remains. There is no evidence that it has been waived or withdrawn by EPA. The requirement is therefore applicable to Ritter.

(iii.) The Weed Resistance Data Was Submitted To, Considered and Relied Upon By EPA

As previously mentioned, the Sparks Report was one of the documents which Monsanto provided to EPA in response to EPA's May 24, 1995 conditional approval of glyphosate for Roundup Ready soybeans. That report, dated August 1995, is titled "The Impact of the Introduction of Roundup

Ready Soybeans on Farmers' Production Costs and Select Environmental Conditions." Monsanto's letter of March 19, 1996 to EPA included a one-volume submission that included this report as well as Monsanto's petition to APHIS seeking non-regulated status for Roundup Ready soybeans and the Federal Register notice containing APHIS's determination of non-regulated status. In its letter, Monsanto informed EPA that it was making this submission to address the concerns which EPA had expressed in its May 24, 1995 conditional approval letter.

The evidence indicates, and we find, that the Sparks Report was designed to address EPA's data requirements in its May 24, 1995 letter. As discussed, that letter addressed the impact of the approval of glyphosate's use on Roundup Ready soybeans, on herbicide use and on cultural practices such as "no-till" or reduced tillage. The evidence also indicates that it was designed to extrapolate results from prior, existing data, such as USDA crop reporting statistics.

It is undisputed that the Sparks Report was received by EPA. It also was reviewed and considered by EPA. See, e.g., EPA's letter to Monsanto of March 20, 1997: "The information submitted to address the conditions of registration of the product for use on glyphosate-tolerant soybeans has been reviewed." The report, however, included estimates of what had occurred in the field and not the actual data. Hence, EPA indicated in its letter that the report had not adequately addressed the effects on reduction of herbicide usage and tillage practices due to the introduction of Roundup Ready soybeans. Monsanto, therefore, supplied additional data to EPA in a further report by the Sparks Company ("Sparks II"). That report was dated June 1996 and was submitted to EPA in December 1997.

Ritter argues that EPA "rejected [the Sparks Report] as insufficient" and never accepted or reviewed Sparks II. Ritter Brief at 29-30. However, the record confirms that EPA not only reviewed the Sparks Report but also wanted to receive more specific data. Monsanto then supplied that data through Sparks II.

Ritter argues that the Sparks Report was "rejected". We find that the Sparks Report was not formally accepted by EPA through its "front-end screen" because the confidential attachment of the report was not properly formatted. Nonetheless, it is clear from the evidence of record, and reasonable inferences we have drawn from that evidence, that the Sparks Report and the APHIS materials, as well as Sparks II, were received by EPA, and were reviewed and considered.

The two Sparks reports did not fully respond to all of EPA's May 24, 1995 data requirements. They addressed only the requirements with respect to short-term herbicide use and tillage and not the longer term potential development of weeds that glyphosate could not control. We have previously discussed EPA's October 23, 1996 letter imposing a requirement for weediness data with regard to cotton and corn. Subsequently, Dr. [REDACTED] learned that EPA had additional concerns regarding weed resistance and continued to require the previously required weed resistance data. The record supports a conclusion that data regarding weed resistance continued to be required in order for EPA to approve the use of glyphosate on any Roundup Ready crop. This was especially true, given EPA's long-term concerns associated with weeds becoming resistant to glyphosate and the potential for resulting environmental harm.

Monsanto's submission of its weed resistance stewardship plans with its petitions for non-regulated status apparently was not sufficient alone to satisfy EPA's weed resistance data requirements. Indeed, during the 1998-1999 time-frame, glyphosate resistant weeds were identified in fields with Roundup Ready crops. The evidence indicates that for this reason, EPA then required Monsanto to meet with it to present additional data on weed resistance to glyphosate.

In response to EPA's requirements, Monsanto undertook a number of field studies and also funded studies conducted by universities that generated weed resistance data. This included the multi-year Benchmark Study, which was conducted at several universities and fully funded by Monsanto. Monsanto then used the data in those studies, particularly the Benchmark Study, in making periodic

presentations to EPA summarizing and explaining the results of Monsanto's weed resistance research.

Dr. testified that Monsanto made these presentations because of its ongoing obligations to comply with the weed resistance data requirements set forth in the continuing conditions of registration. His testimony was not controverted at the hearing.

The record indicates that Monsanto's presentations to EPA regarding weed resistance started in about 1999 and continued through at least 2010. They included the use of Power Point materials. Dr.

attended all of the presentations with EPA. At the presentations, Monsanto discussed with EPA the results of the weed resistance research it was conducting, the educational and training programs implemented in the field to address the issues, and label modifications which were being made to incorporate weed resistance management measures which had been developed based on Monsanto's research. EPA's comments and questions at the presentations were often incorporated into Monsanto's ongoing data generation efforts regarding weed resistance. Our review of the record confirms that these presentations included summaries of Monsanto's weed resistance data on SOC Exhibit 4 and, in particular, summaries from the Benchmark Study. The record indicates that EPA remained concerned and continued during this period to require data from Monsanto to satisfy its requirements regarding weed resistance. Monsanto sought to satisfy those requirements through its presentations and, as further discussed below, also through label revisions incorporating practices to reduce potential weed resistance.

We have discussed our conclusions on compensability of "weediness" data above. We incorporate that discussion here. In addition, we have discussed here other considerations particularly relating to weed resistance. We conclude that there is significant record evidence that the summaries of Monsanto's weed resistance data are "in the Agency's files" and were considered by EPA to support the use of glyphosate on glyphosate-tolerant crops. We make this finding based on the evidence presented and the reasonable inferences we have drawn from that evidence.

Ritter claims, apparently as to both the SOC Exhibit 3 and SOC Exhibit 4 data, that the data are not compensable since the submission dates to EPA are not evident. Ritter Brief at 74. However, this is not an issue in this case. EPA initially imposed the data requirements in its May 24, 1995 letter (Ex. 57) and Ritter has conceded that the 15-year compensability period began on February 9, 1990. Ritter Brief at 73-74.

Finally, if Ritter had been the initial registrant in 2005 for the new use of glyphosate on glyphosate-tolerant crops, we have no doubt that EPA would have required from Ritter similar, if not more, data regarding weed resistance. This conclusion is inescapable, given the record evidence, and an assumption of reasonable, prudent Agency action. See 40 C.F.R. 152.86(d)(2)(ii).

(iv.) The “Public Literature” Compensability Exception Does Not Apply

Section 3(c)(1)(F) of FIFRA exempts from data compensation “data that appear in the public literature.” This does not mean, as Ritter has so vigorously argued in opposing compensability of SOC Exhibits 3 and 4 data, as well as certain Exhibit 2 data (such as Study No. 143), that this section also exempts data or literature that are “publicly available.” Ritter Brief at 67-73. The distinction between what may be in the “public literature” and what may be “publicly available” is an important one for purposes of FIFRA compensability.

By way of background, FIFRA Section 10(d)(1) requires that certain data must be available to the public: “All information concerning the objectives, methodology, results or significance of any test or experiment performed on or with a registered or previously registered pesticide or its separate ingredients . . . and any information concerning the effects of such pesticide on any organism . . . shall be available for disclosure to the public.” However, that section also provides that “[t]he use of such data for any registration purpose shall be governed by section [3] [i.e., the data compensation provisions] of this title.” Id. This means that, while certain data that support a registration or new use

registration must be publicly available, the data compensation obligations of a subsequent registrant such as Ritter do not change. Public disclosure does not control the right of a data owner to be compensated. Rather, this is controlled by Section 3 of FIFRA, which requires compensation.

The public literature exception to compensability in FIFRA was designed to prevent a data submitter from mining publicly available journal articles which it did not fund, and/or government-generated or government-funded studies, citing to them in its registration applications and then claiming that a follow-on registrant owed them data compensation for the materials. The “public literature” exception, however, does not limit the rights of a data submitter that paid for the creation of data that were later incorporated into publicly available materials. We have no trouble concluding that EPA did not intend proprietary data to become non-compensable if it is also made publicly available. Mr. Tinsworth so testified. That view finds support in the legislative history of FIFRA. It also, of course, makes common sense. See 49 Fed. Reg. at 30,896.

Ritter, however, argues against compensability of some data claimed in SOC Exhibit Nos. 3 and 4, characterizing it as “public literature.” According to Ritter, “there is no difference between the phrases ‘publicly available’ and the 40 CFR 152.94 phrase ‘public literature.’” Ritter Brief at 69. Ritter maintains that once data is made public, there is no longer an entitlement to exclusive use of the data nor is there an entitlement to compensation. Id. In particular, Ritter references several weed resistance studies summarized in journal articles and “weediness” data that appears on APHIS’s web site and in published journal articles. Ritter addresses many of the study results in the “Additional Studies” shown in SOC Exhibit 4, including the Benchmark Study. Ritter asserts that these were published in the public literature. It further argues that all of them were generated by public universities. On this basis it claims non-compensability because the data were government-generated. Id. at 71. We cannot accept Ritter’s view.

As argued by Monsanto, the key question here is whether Monsanto “generated the data, paid for its generation, or otherwise [has] legal ownership of the data.” 49 Fed. Reg. at 30, 896. We are satisfied that the record evidence fully supports that this is the case for the data for which Monsanto claims compensability. Monsanto paid universities and other third parties to generate the weed resistance data.¹¹ Monsanto generated the “weediness” data or otherwise paid for their generation. Moreover, we find record support for the reasonable conclusion that journal “articles do not contain sufficient information, in themselves, to satisfy a registration data requirement.” 49 Fed. Reg. at 30,896. Rather, as is the case here, since Monsanto generated the underlying data, paid for it to be generated or otherwise legally owns the data, it is entitled to be compensated for it. The “public literature” exception simply does not apply.

Simply put, Ritter’s arguments regarding this subject were not persuasive.

c. Directions for Use Data Claim

As indicated above, SOC Exhibit 4 includes a claim for data generated by field studies and protocols related to Monsanto’s development of directions for use for glyphosate on glyphosate-tolerant crops. Directions for use are a specific component of a pesticide label that provide instructions for a grower or other end user as to the amounts, frequency, method and application for each individual use on each individual crop for which the pesticide has been approved by EPA for use. Monsanto developed its directions for use through scientific research conducted by Monsanto’s technical development group and through the development and implementation of protocols and field studies.

¹¹ Even in those instances where university documentation in the record refers, for example, to Monsanto’s payments to the universities being in the nature of grants or unrestricted gifts, that the universities considered it necessary for their own purposes to characterize the payments in this kind of way does not alter the fact that Monsanto paid for the studies. In this regard, Monsanto’s accounting expert, Mr. Keenan, testified that “the university provided the service, and Monsanto paid for it . . . we have documentation with respect to these costs.” Tr.at 3610:8-3611:15. Moreover, the record indicates that Monsanto did not treat the payments as charitable contributions for tax purposes.

Those directions for use were then incorporated into product labels which were then submitted to EPA for approval. Label changes related to directions for use also had to be submitted to EPA and approved.

There is no dispute that the subject directions for use which Monsanto developed and displays on its glyphosate products are also used by Ritter on its glyphosate products. Ritter has not independently conducted any studies or developed its own directions for use. Ritter asserts, however, that the directions for use studies are not compensable under FIFRA.

Monsanto maintains that its directions for use data are compensable for two essential reasons. The first reason is that directions for use data are required for food use pesticides by Part 158 residue chemistry requirements. See 40 C.F.R. 158.1410. Monsanto points out that the residue chemistry data requirements include Guideline Number 860.1200 for directions for use. 40 C.F.R. 158.1410. Relying in part on Ms. McGaughey's testimony, Monsanto thus asserts that directions for use "are FIFRA data, are a data requirement applicable to every food-use pesticide registration (including Ritter's glyphosate registrations), must be submitted to EPA, and are compensable." Monsanto Brief at 71.

Monsanto's second reason in support of compensability is that directions for use are part of tolerance petitions submitted under FIFRA and FFDCA. See 40 C.F.R. 158.130(i)(3); 21 U.S.C. 346a(d)(2)(A)(iii). According to Monsanto, and as previously discussed, the data required by EPA to establish a new tolerance or to amend a tolerance are included in a tolerance petition. Monsanto points out that such a petition must include "data showing the recommended amount, frequency, method, and time of application of that pesticide chemical." 21 U.S.C. 346a(d)(A)(iii); see also 40 C.F.R. 180.7(b)(4). As Ms. McGaughey testified, these data are directions for use data. Citing 21 U.S.C. 346a(i)(1), Monsanto thus maintains that such data are compensable under FIFRA. Monsanto Brief at 71.

Ritter makes several arguments as to why these data are not compensable. First, it claims that if there is a Part 158 residue testing requirement, as Monsanto asserts, the directions for use studies should have been included in SOC Exhibit 2. Ritter Brief at 36. In effect, Ritter asserts that Monsanto's

decision to place the studies in SOC Exhibit 4 shows that Monsanto recognized that the studies are not required by Part 158 guidelines and are akin to what Ritter asserts is voluntary, non-compensable label material, such as weed resistance management material.¹² We are not persuaded by Ritter's SOC "placement" argument. Monsanto's decision, for claim presentation purposes, to include this data in SOC Exhibit 4 has no legal significance. Moreover, the data include weed resistance management studies and thus relate to Monsanto's larger claim for weed resistance data in SOC Exhibit 4.

Ritter next argues that its label and directions for use are non-compensable "administrative materials." Ritter Brief at 34-35. Ritter claims that Mr. Tinsworth identified them in this way at the hearing. Our review of the referenced transcript section, however, indicates his response to Monsanto counsel's general request to identify an exhibit was not directed to the specific issue whether directions for use are non-compensable "administrative materials." We do not think that drawing an inference to that effect from this testimony is warranted. In any event, we find that they are not "administrative materials."

In opposing compensability of directions for use data, Ritter also asserts that directions for use do not meet the definition of "tests or results thereof" in Section 3(c)(1)(F) of FIFRA. Ritter Brief at 34. We do not agree and find, as Ms. McGaughey testified, that directions for use reflect the results of the tests which were conducted. We also find that the results are submitted to EPA through the pesticide label and also through tolerance petitions. This, we believe, is in accord with FIFRA. Ritter contends that Monsanto must show that it is entitled to exclusive use of the directions for use data and that it is not available to the public. Ritter Brief at 37. We do not agree. It is sufficient that Monsanto

¹² We note that we previously found that Monsanto's weed resistance management data is not voluntary and is compensable. Although Ritter also contends that weed resistance data are not compensable because weed resistance labeling under PR Notice 2001-5 is purely voluntary (Ritter Brief at 32-34), the requirement for Monsanto to develop weed resistance data, including weed resistance management data, stems from EPA's conditional approvals and other requirements which were imposed on Monsanto. Moreover, PR Notice 2001-5 concerns generic labeling requirements that are not specific to glyphosate.

developed, paid for or owns the data. It also is of no moment, for reasons previously discussed, that the directions for use data allegedly were not formatted as data when presented to EPA and did not receive MRIDs.

testified that had not included directions for use data in data matrices she prepared for other companies and that EPA had not asked for the data. Id. Again, we do not find this persuasive. As we discussed, the applications prepared by generally used the "cite-all option" under the "selective" method. These applicants submitted general offers to pay and Certifications to EPA. EPA thus would not have been especially concerned about the completeness of their data matrices.

In addition, as mentioned above, the data requirements for residue chemistry are listed in 40 C.F.R. 158.1410 and directions for use are included there. Guideline No. 860.1200, titled "Residue Chemistry Test Guidelines OPPTS 860.1200 Directions for Use", provides that "[t]his guideline is intended to meet testing requirements of both [FIFRA] and [FFDCA]."

We also are not persuaded by Ritter's argument that directions for use are referenced in a different section of the registration requirements which do not concern compensability. Ritter cites FIFRA Section 3(c)(1)(C) which, according to Ritter, simply provides that applicants are to submit directions for use for their product on their labels: "Directions for use are ordinarily contained in specimen labeling submitted concurrently for registration." Id. This mention of directions for use in Section 3(c)(1)(C) does not, we believe, change the fact that there are specific legal bases, as discussed above, which establish that directions for use are compensable under FIFRA.

Finally, we find that directions for use are not "efficacy" data (which are non-compensable). See 40 C.F.R. 158.400. They are not simply data which concern how well the product performs and how effective it is for its intended purposes. To the contrary, for the reasons we have discussed, directions for use clearly are required data and are compensable under FIFRA.

d. Summary of SOC Exhibit 4 Claims

For all of the above reasons, we have determined that Monsanto has met its burden of proof as to the compensability of the studies in SOC Exhibit 4. The amount of the compensation to be owed by Ritter to Monsanto for the studies will be determined later herein.

5. Regulatory Management Costs

Monsanto's SOC Exhibit 1 includes a claim for \$3,616,433.00 in Regulatory Management Costs. That figure amounts to 20 percent of its claimed base costs for SOC Exhibit 2 studies. This is basically a claim for recovery of corporate overheads associated with the direct costs presented for those studies. Monsanto supported this cost element with testimony from William Keewan, its accounting expert. Using accounting records provided by [redacted] and descriptions of regulatory management activities provided by [redacted] Monsanto's regulatory manager for glyphosate, Mr. Keewan performed a study that indicated these overheads could have exceeded \$4.5 million. On this basis, Monsanto urges that its use of the 20 percent factor applied to the base costs produces a reasonable estimate of \$3,616,433.00 for these costs. Monsanto Brief at 79-80.

Ritter acknowledges that including compensation for regulatory management overheads can be appropriate, but argues that Monsanto did not satisfy its burden of proof with the evidence it provided, saying that, to be allowable, such costs must be shown to be actual costs for each piece of required data in SOC Exhibit 2. It urges that recovery of a company's general administrative costs not tied to the generation of particular data is not allowed under FIFRA. It would not include any amount for regulatory management costs in the Award. Ritter Brief at 12.

The Panel has concluded that allowing recovery of a component for corporate overheads is entirely appropriate in establishing compensable costs under FIFRA. Recognition of such costs is widely recognized in the field of cost accounting. Although not binding on us, we note that it has previously been done in a number of other FIFRA arbitration awards. See Amvac Chem. Corp. and Termilind, Ltd.

et al., No. 23-171-00002-96 (Oct. 26, 1999) at 7; Cheminova A/S and Griffin L.L.C., No. 23-171-00020-99 (June 29, 2001) at 11-13; E.I. DuPont de Nemours & Co. and Griffin Corp and Drexel Chem. Corp., No. 16-171-00080-86M (Dec. 22, 1988) at 18; Monsanto Company and Tacoma Ag, LLC, *supra*, at 40.

The remaining question is the amount to be allowed for these costs. Monsanto has presented an analysis prepared by a qualified expert, using data from its own accounting records, and supported by descriptions of management activities from a witness with long-time involvement in the regulation of glyphosate. Ritter has proposed disallowing these costs entirely and did not present evidence on alternative calculation. As with our conclusions on the issue of discounting estimates, we conclude that Monsanto's witnesses have adequately supported use of an allowance for Regulatory Management Costs based on application of a twenty percent factor to allowed SOC Exhibit 2 costs.

Accordingly, for all of the above reasons, we have determined that Monsanto has met its burden of proof as to the compensability of the claimed Regulatory Management Costs. The amount to be owed by Ritter to Monsanto for these costs will be determined later herein.

6. EPA Tolerance Application Fees

Monsanto seeks \$147,375.00 as a cost that it incurred for the payment to EPA of tolerance fees. The fees were paid by Monsanto between May 26, 1994 and March 19, 2003. They were assessed by EPA when Monsanto filed applications for approval of certain tolerances as required by EPA.

Ritter objects to their inclusion primarily on the basis that tolerance fees were no longer being assessed by EPA in 2005 at the time Ritter received its initial registration of glyphosate. Ritter Brief at 12-13. Ritter is not entirely correct since tolerance fees, from October 1, 2003 through September 30, 2008, essentially became a part of the fees collected under the Pesticide Registration Improvement Act of 2003 ("PRIA"). *See* 40 C.F.R. 180.33(o). As a result, pursuant to PRIA, tolerance fees were replaced by fees for so-called "tolerance actions" and were collected in 2005. Here, it does not matter that fees for "tolerance actions" or "tolerance applications" are compensable for the period October 1, 2003 through

September 30, 2008. As indicated, Monsanto's claim for tolerance application fees is limited to an earlier period.

Ritter also argues that these fees cannot qualify as compensable data since there is no authority for tolerance fee compensation in Section 3 of FIFRA. It is not mentioned in the preamble and these fees are not addressed in data submitter's rights in the regulations. Ritter Brief at 13.

We find it perplexing that Ritter has stipulated to the compensability of all of Monsanto's domestic residue and tolerance studies in SOC Exhibit 2 (Ritter Brief at 38) but objects to Monsanto's claim for the fees it was required to pay to EPA in order to file the tolerance petitions which were supported by those studies. We have previously determined in this Award that the data and studies supporting the tolerance applications are compensable. We find that the claimed tolerance fees are a legitimate component of costs of applying for and maintaining applications for the use of glyphosate, and should be included as part of the awarded compensation. They were required by EPA and an actual cost incurred by Monsanto to submit tolerance data and secure relevant tolerances from EPA. Although not binding on us, we note that arbitrators in other FIFRA cases also have concluded that tolerance fees are a compensable component of costs of studies and data. See Proem, Ltda and Grapetek (Pty), Ltd., Case No. 23 171 00027 98 (1999) at 24 and Monsanto Company and Tacoma, AG, LLC, supra at 41.

Accordingly, for all of the above reasons, we have determined that Monsanto has met its burden of proof as to the compensability of the claimed tolerance application fees. The amount of the compensation to be owed by Ritter to Monsanto for these fees will be determined later herein.

7. Monsanto's Use of Estimates In Calculating Costs.

Monsanto used estimates to calculate base study costs for studies listed in SOC Exhibits 2, 3 and 4. Estimates were used in the cost calculation of studies prepared in-house by Monsanto personnel, as well as third-party costs when contemporaneous records, such as invoices, were not available. Contemporaneous records were used when available. They included third-party vendor invoices,

project cost estimates, correspondence, quotations, proposals, cancelled checks and Monsanto's "generic budget." For in-house costs, estimates were based on personnel costs, such as salary and overhead.

The SOC Exhibit 2 breakdown of internal and external costs is contained in Claimant's Exhibit 2. The base costs for each study summarized in SOC Exhibit 2 are the sum of Monsanto's total external and internal costs for each study. The external study costs comprise either third-party costs derived from invoices and other documents or cost estimates. Those estimates were prepared by Monsanto employees, Dr. [REDACTED] and [REDACTED] both of whom are scientists and personally involved in many of the studies. Ms. McGaughey also prepared some of the estimates. Dr. [REDACTED] had 28 years of experience conducting studies. She testified that the internal costs, including the estimated man-months required for each study, were based on an annual full-time equivalent (FTE) rate applied to the estimated man-months that would be required. FTE was derived from internal records.

Dr. [REDACTED] and Ms. McGaughey provided detailed testimony supporting the costs of the Exhibit 2 studies, both internal and external. Another Monsanto employee, [REDACTED] also provided detailed testimony about the source information and methodology for calculation of FTE used in the Exhibit 2, 3 and 4 studies. All of this testimony was supported by the testimony of Monsanto's accounting expert, William Keegan. Mr. Keegan is a CPA with four decades of experience in accounting, which includes FIFRA and cost accounting for government contracts. He was accepted as an expert in the determination and calculation of costs, estimates, use of FTE, and adequacy of records. Mr. Keegan testified that the use of estimates in SOC Exhibits 2, 3 and 4 was acceptable and consistent with reasonable and generally accepted cost accounting principles. He provided his opinions after reviewing the Statement of Claim, the Statement of Position, discovery responses, pleadings, various FIFRA cases, regulations and the direct testimony of [REDACTED] and [REDACTED]. He also personally interviewed a number of Monsanto's employees, including some of the above. He

also interviewed Ms. McGaughey and reviewed, and explained the contents and compilation of, Claimant's Exhibit 27 which contains the study costs' supporting documents. Mr. Keevan testified regarding the acceptance of the use of estimates when contemporaneous records are not available, citing a number of sources, including the Codification of Statements on Auditing Standards (Exhibit 195), Government Contract Costs and Pricing (Exhibit 193), the American Institute of CPA-Audit and Accounting Guide (Exhibit 197). His detailed methodology is contained in Claimant's Exhibit 28.

Ritter's accounting expert was [REDACTED] CPA. [REDACTED] was experienced in forensic accounting, business evaluation and damages analysis. [REDACTED] had been qualified as an expert in various state and Federal courts but had not previously testified, or been involved, in a FIFRA case. [REDACTED] was retained by Ritter in October, 2012 and testified during the December, 2012 hearings. We have weighed those constraints on [REDACTED] opportunity to prepare here in our consideration of the evidence on this issue. Although [REDACTED] testified that Monsanto's estimates were not "testable", [REDACTED] also testified that [REDACTED] had not reviewed the testimony of Ms. McGaughey or Dr. [REDACTED] and also had not reviewed Mr. Keevan's work papers or methodology. [REDACTED] offered no opinions as to the FTE. Moreover, [REDACTED] candidly testified that estimates are appropriate in certain circumstances, and that [REDACTED] has used them.

SOC Exhibit 3 costs were derived from the "generic budget", an internal Monsanto budget that was completed during the summer of 2012. It represents present day costs and thus was not adjusted to reflect the cost of money. We find the "generic budget" to be a reliable basis for determining Monsanto's costs since it (a) was prepared during the ordinary course of Monsanto's business, (b) underwent several layers of review, (c) was based on recent historical costs of the company, and (d) is a summary of the costs needed to launch a new Roundup Ready crop (generally categorized based on scientific discipline or type of functions) expected to be incurred by Monsanto's regulatory group to obtain U.S. and import approvals. Furthermore, Monsanto senior management used the generic budget

in determining long-term financial plans and corporate investment strategy. Monsanto provided testimony from several employees, including [REDACTED] and [REDACTED] regarding Monsanto's use of the "generic budget". The reliability of the "generic budget" in determining costs was also supported by the testimony of Mr. Keevan, Monsanto's accounting expert. He noted how rigorous the budget process is and opined that it provided a reasonable basis for determining the costs in SOC Exhibit 3 in accordance with generally accepted accounting and cost determination practices.

Regarding SOC Exhibit 4, the internal costs for the field studies Monsanto conducted were derived by applying an FTE rate to the man-years required to conduct each study. Mr. Keevan calculated that rate based on information provided to him by Ms. [REDACTED]. Man-years per study were calculated by applying the total number of sites per study to the number of man days per site and then converting total man-days into man-years. He testified that the estimate of man-days per site provided by Ms. McGaughey was reliable from an accounting perspective, that the manner of converting man-days to man-years was reasonable, and that the calculation of FTE rates employed a reasonable methodology. Ms. McGaughey also testified, based on her own experience, that the costs for the field studies were reasonable. None of this testimony was persuasively controverted by Ritter at the hearing.

As earlier discussed, SOC Exhibit 4 also included "Additional Studies", including the multi-year Benchmark Study. These studies were conducted primarily by universities. Dr. [REDACTED] Monsanto's Product Manager for weed resistance, testified about these studies and introduced the company's payment records and other business records which documented these costs. Mr. Keevan testified that these records provided a reasonable basis for determining the costs of these studies.

Monsanto also presented evidence for its claimed internal costs to manage and implement the weed resistance studies in SOC Exhibit 4. Mr. Keevan provided information regarding internal man-years worked by Monsanto and FTE rates, stating that they were based on information which Monsanto had provided to him. He indicated that the rates were then applied to man-years in determining internal

costs. Mr. Keevan provided his opinion that the methodologies used to calculate FTE rates for this group of costs were reasonable. His testimony was not controverted, and we find it to be reliable.

Finally, with regard to Monsanto's tolerance application fees, the record includes acceptable documentation of those costs.

Thus, it is clear that Monsanto heavily relied on various kinds of estimates to support its claimed costs in this proceeding. Monsanto's case for the use of estimates in the absence of contemporaneous records is convincing. Unlike some professions, Monsanto's record-keeping system does not require detailed personnel time to be recorded on a project by project basis, and we conclude that its lack of contemporaneous records was justified. We find that Monsanto's estimates were reasonable and based on credible personal knowledge, assumptions and previous experience in conducting and supervising studies. We further find that the methodologies used and explained by Mr. Keevan were sound.

did not undertake an investigation of the formulation of the estimates. Nor did attempt to discredit the methodologies that Monsanto employed. Nonetheless, and notwithstanding all of the evidence and expert opinions which Monsanto provided to support its estimates, Ritter argues that Monsanto should have used actual cost data and that its estimates are biased and unreliable. Ritter Reply at 16-17. Although Ritter conducted vigorous cross-examination of Mr. Keevan and Monsanto's other witnesses, and that testimony revealed some minor "discrepancies", it did not persuade us that Monsanto's estimates are unreliable and should not be accepted. We did not find any indication that the estimates were biased. That conclusion was reinforced by the evidence discussed above concerning the internal discipline associated with preparing estimates for the corporate budget process.

Ritter did not ask us to reject Monsanto's estimates "outright". Rather, it requests that we discount the compensation to be owed by Monsanto by 20% in light of its heavy reliance on estimates and because it did not have or use records of its actual costs. In support, Ritter cites to rulings by other

FIFRA arbitration panels, including, most recently, the Tacoma panel, which applied 20% or 25% discounts to estimates. Ritter Brief at 78. Our review of those rulings, however, underscores the fact that each case is dependent on the evidence as established. Here, Monsanto presented a substantial body of evidence, including from its accounting expert, regarding the estimates which it used and established their reliability. We are satisfied that Monsanto has met its burden of proof in establishing its claimed costs, including through its use of estimates. We do not find that there is sufficient evidence in this case to overcome Monsanto's extensive research, experience and its methodologies in compiling its estimates. Ritter did not present sufficient evidence to rebut the accuracy or reliability of the estimates or to justify application of a discount. Accordingly, we shall not apply a discount to Monsanto's estimates in this case.

8. Interest Claim

Monsanto is seeking to recover interest with regard to the costs it expended to generate the data included in SOC Exhibits 2 and 4, except for the costs which were estimated by its experts. Monsanto asserts that FIFRA requires follow-on registrants, such as Ritter, to pay compensation to the data originator which covers not only direct costs to generate the data, but also what Monsanto characterizes as "other implicit, legitimate components of the costs of generating the data." Monsanto Brief at 84. Monsanto alleges that these other components include the cost of raising the capital needed to pay for the studies. It claims that the best measure of that cost is the prime rate of interest. According to Monsanto, it is the closest measurement of the cost of raising capital through equity financing, long term debt or retained earnings. Monsanto asserts that using the prime rate would be a conservative approach since its cost to raise capital under each of these methods was at least as expensive as the prime rate. Monsanto believes that using inflation alone as a measurement would "fail to fully capture the time value of money . . . , [and] omits the costs of raising the capital necessary to generate the data at issue." Monsanto Brief at 87. Monsanto relied primarily on the testimony of its

expert, Dr. Erik Lichtenberg, an economist and professor in the Department of Agricultural and Resource Economics at the University of Maryland, in advancing its claim to recover interest based on the prime rate. It also relied on testimony from its accounting expert, Mr. Keewan.

Monsanto maintains that an award of interest also is appropriate because Ritter used dilatory tactics to delay the evidentiary hearing and cites the earlier discussed hearing continuances granted by the Panel related to [REDACTED] and the withdrawal of its original counsel, DLA Piper. Monsanto alleges that these “obvious and unreasonable” efforts to delay the hearing justify inclusion in the Award of an amount akin to pre-judgment interest. In support, it cites several cases, *i.e.*, Kaseman v. District of Columbia, 329 F. Supp 20, 28 (D.D.C.2004); Fresh Kist Produce, LLC v. Chloi Corp., 251 F. Supp. 2d 138, 143 (D.D.C. 2003) and Clinchfield Coal Co. v. Fed. Mine Safety and Health Review Comm’n., 895 F. 2d 773, 779 (D.C. Cir. 1990).

Ritter does not oppose application in this proceeding of an appropriate inflation adjustment in calculating the Award amount and presented testimony from its accounting expert,

to advance its position. Ritter Brief at 80-81. In addition to opposing the use of an inflation adjustment rather than interest at the prime rate, Monsanto also claims that [REDACTED] omitted Monsanto’s regulatory management costs in [REDACTED] calculations and improperly calculated inflation from a study’s submission date rather than from its completion date. Monsanto also argues that if an inflation adjustment approach were to be adopted by the Panel in this case, it should not be based on the Bureau of Economic Analysis (“BEA”) deflator (the “GDP”), the approach used by [REDACTED] but one based on the Bureau of Labor Statistics Employment Cost Index (the “ECI”). Monsanto Reply at 32-33.

Ritter generally cites Ruckelshaus v. Monsanto Co., *supra*, for the proposition that the measure of compensation under FIFRA should be limited to the recovery of costs and should not include a measure of return of profit. It also cites the award in Tacoma, *supra*, in arguing that the appropriate measurement is one limited to inflation, such as the GDP deflator. It argues that the prime rate includes

opportunity costs for a return on profit which might result in a double return and thus violate the intent of Congress in adopting FIFRA. Ritter also claims that Monsanto itself delayed in pursuing its FIFRA claim in arbitration for three years, as opposed to the eight month hearing commencement delay related to [redacted] and its change of counsel. It maintains that Monsanto's claim of dilatory tactics is unfounded and unjustified. Ritter Reply at 17-19.

[redacted] testified that [redacted] inflation adjustment calculation tables, Respondent Exhibits 1100 and 1101, were based on GDP deflator numbers from the BEA that [redacted] obtained from Bloomberg reports. Monsanto asserts that [redacted] did not apply the appropriate BEA numbers since BEA changed its numbers before [redacted] testified. Monsanto also objects that [redacted] did not provide documentation of the deflator-related search parameters [redacted] used or any other information which would permit Bloomberg's work product to be examined. According to Monsanto, [redacted] also had no explanation as to why [redacted] considered that the rates [redacted] used were not the same during each month of a given quarter even though Bloomberg reports the same level of inflation for three continuous months until BEA changes the rate. Monsanto Reply at 32-33. More importantly, relying on the testimony of Dr. Lichtenberg, Monsanto argues that the GDP deflator which [redacted] used measures personal consumption and defense spending rather than "the costs of scientists and technicians who do the work of producing data." Monsanto Reply at 33. He testified that the ECI is a more appropriate measure of these kinds of costs. Monsanto urges the Panel to adopt the ECI approach if it does not adopt the prime rate.

We do not find use of the prime rate to be an appropriate way to measure the cost of money in this proceeding. Although not binding on us, we note that the panel in Tacoma reached the same conclusion. See Monsanto Company and Tacoma Ag, LLC, supra, at 44-45. For the reasons mentioned above, we agree with Ritter that this cost should be measured based on an adjustment for inflation. However, we agree with Monsanto that the calculations should run from the date of completion of a study and not the date of submission of a study since the former more accurately measures when

Monsanto actually expended the costs. The Panel agrees with Monsanto that the index that is more appropriate in this case is the ECI since it more appropriately concerns costs for the work of scientists and technicians than the more consumer-oriented GDP. The costs incurred by Monsanto were primarily costs for the work of scientists and technicians. We find, therefore, that the ECI is a more accurate measure of the time value of the money spent by Monsanto for the compensable studies. We will employ this measure in our Award in calculating the amount to be recovered by Monsanto in this proceeding. In this regard, the record includes calculations based on use of the ECI which Dr. Lichtenberg prepared. We find those calculations to be reliable.

Finally, in our determination of costs for the time value of money, we do not find any need to take into account the alleged delays by either party in connection with this arbitration proceeding.

Accordingly, for all of the above reasons, we have determined that Monsanto has not met its burden of proof as to the compensability of the claimed amount for interest based on use of the prime rate. The amount of the compensation to be owed by Ritter to Monsanto shall instead be based on an adjustment for inflation. This shall not be based on the GDP as Ritter requests but on the ECI as Monsanto alternatively has requested. The amount of this compensation to be owed by Ritter to Monsanto will be determined later herein.

9. Premium

Monsanto's claim includes a component which it characterizes as a "75% risk Premium." Monsanto's Exhibit 1, its "Summary of Claim Calculation," lists it in a section labeled "Additional Compensation Elements" that contains two components: "Interest" and "Premium." The Premium amount shown is \$65,897,139.00, which is 42.86% of the total claim prior to allocation to Ritter.

In a tacit recognition that the data compensation provision of FIFRA is a cost recovery system for the pioneer registrant of a product, Monsanto's hearing presentation supporting this component of its claim seeks to justify the premium as the cost of a self-insurance program against certain risks involved

in generating the data that supports the registration of glyphosate.¹³ The risks are characterized as the need to repeat studies, to conduct follow-on studies or new studies, and the possibility of outright rejection of all studies supporting a use or uses of glyphosate.

Monsanto presented expert testimony by Dr. Lichtenberg to support its position. He testified that he undertook an analysis which identified the types and sources of risk that Monsanto faced in gaining EPA approval and purported to quantify these regulatory risks. This was done by analyzing data on EPA rejection rates for various types of data and calculating what Monsanto called “an estimated actuarially-fair premium rate range for Monsanto’s data.”

Ritter challenged the allowance of any premium amount in this arbitration. It pointed to recent FIFRA arbitration awards that have rejected this claim element. Tacoma, *supra*, at 51; BASF Corp. and Albaugh, Inc., FIFRA No. 23 171 00040 00 (Mar. 22, 2002); Spray Drift Task Force and Burlington Bio-Medical Corp., FIFRA No. 16 171 Y 00474 03 (Aug. 24, 2005). It pointed to its inconsistency with the cost-related concept that underlies Congressional intent in providing for data compensation. Ritter also attacked the validity of Dr. Lichtenberg’s statistical analysis seeking to justify the premium as a self-insurance cost.

The Panel will not discuss the details of Monsanto’s self-insurance analysis here because it is clear at the threshold that Monsanto’s justification for this premium is unsound as a basic matter of financial theory. Unquestionably, Monsanto’s endeavor to obtain the necessary regulatory approvals to bring glyphosate to market for the uses it designated required the assumption by Monsanto of certain investment risks. However, the avenue through which the cost of such risks is recovered is the return

¹³ In other arbitrations, Monsanto has proffered justification for a premium based on the benefits obtained by follow-on glyphosate applicants from the outcome of Monsanto’s own highly risky efforts to obtain the glyphosate registrations on which the follow-on applicants rely. See, e.g., discussion in Tacoma, *supra*, at 44-45. Monsanto offered no such rationale for the premium in this proceeding, either through its expert testimony or in the arguments in its briefs. Here, its case on the premium rises or falls on the validity of its “cost of self-insurance” analysis.

earned by the investor on its capital. When conventional insurance arrangements are available to spread some of those risks beyond Monsanto's investors, it would be appropriate to recognize the cost of that insurance as a cost of doing business. However, the capital markets would recognize that reduction in the risk to investors in the enterprise itself and the market cost of Monsanto's capital would be lower. Monsanto's theory seeks to equate the cost of self-insuring against those investment risks with the cost of obtaining commercial insurance covering them. However, using self-insurance in these circumstances does nothing to spread the risk beyond the corporate investors and the capital market would see no change in the risk. Moreover, Monsanto's witness expressly testified that, in his opinion, commercial insurance covering the regulatory risks he addresses would not be available.

It might be argued in these circumstances that the premium sought by Monsanto could be justified as a cost of capital based on the regulatory risks to which Monsanto refers. However, Monsanto did not make that argument and it offered no evidence supporting the premium as a cost of Monsanto's capital in the financial markets. The Panel sees no merit in that justification, even if it had been offered. It is far from evident that Monsanto should be viewed, from an investor perspective, of being in the business of obtaining regulatory approval through data submissions so it could recover its research costs from others. Rather, Monsanto raises its capital to support the process of developing and selling certain types of products for uses in the agricultural field. From this perspective, the fact that it might recover some of its research costs from sources other than product sales is certainly "the tail wagging the dog" in the capital markets.

In any event, Monsanto made no attempt here to justify its premium by analyzing its cost of capital. Nor did it present any legal justification along those lines through citation to other FIFRA awards. Monsanto has the burden of proof on justifying the premium element of its claim and it has not met that burden. Its self-insurance theory is faulty and it made no attempt to justify it as a capital cost.

Accordingly, we will not make any adjustment for a risk premium to the direct costs of Monsanto determined to be compensable here.

10. Ritter's Allocable Share of Compensable Costs

One task remains in determining the data compensation to be awarded to Monsanto here. An appropriate portion of the total compensable amount determined above must be allocated to Ritter's responsibility. Two potential allocation factors have been considered in other FIFRA arbitrations: market share and *per capita*. Here, both parties agree that the *per capita* method should be used, but they differ widely as to the resulting appropriate head count, although they both start with a data base that shows all currently active glyphosate registrations, both technical acid and end uses. We will use the *per capita* method and will start with that data base.

As a first step, we noted that the data base presented data on active glyphosate registrations, listing them by individual registration numbers, but indicating the name of the registrant for each one. Many companies are listed as holding a number of registrations. We have determined to base the head count on the number of registrants, not registrations. This makes sense in the context of the FIFRA data compensation scheme, which provides for negotiation, or arbitration, if necessary, to determine the compensable amount due from an entity relying on previously submitted data. This implies company by company determination of data use rights, rather than repeated dealings on individual registrations. Indeed, the record here clearly indicates that when a final compensation arrangement is put in place, it covers a general right for the follow-on applicant to rely on the pioneer's data filed at EPA (although rights to use future data supplied by the pioneer may not be covered in some circumstances). Thus, it makes sense to count the number of corporate entities involved in the registration process, not the number of registrations they accumulate for a particular chemical product.

This makes it necessary to extract from the data base presentation of registrations the names of the companies that hold those registrations. Monsanto did this in Appendix 32 to its Reply Brief,

producing a list of 123 names. Ritter proposed including all of them in the head count, while Monsanto proposed elimination of names based on certain categories. We will examine the company names presented in Monsanto's Appendix 32 to its Reply Brief and consider their treatment in the allocation factor. In the discussion of that examination below, references to Award Appendix refer to Appendix A to this Award, where the results for each name are annotated to this text.

Before addressing the categories to be considered for exclusion, we made a preliminary adjustment. We eliminated instances where a particular company already designated for inclusion in the head count was listed more than once as the holder of an EPA registration number. For instance, Monsanto itself has two numbers. A total of twelve such duplications were identified. Award Appendix A, Key 1. In cross-checking for this purpose, we also noted and added two companies identified in the registrations list that did not appear in Monsanto's Appendix 32. These are appearing on p. 18 of Monsanto Ex.385A, and appearing at p. 26 thereof. There is also one company, which we will include in the head count, which is not on either Appendix 32 or in Monsanto Ex. 385. With those initial adjustments, the starting point for our analysis of categories for elimination is 114 names.

As noted, Ritter would simply use the full roster of registrants as the per capita allocation factor. Before adopting such an approach, it is necessary to consider and analyze the adjustments to that roster Monsanto proposes. It presented four screens to be applied to the list of registrations. We have considered each of them to determine whether they should be applied to eliminate names from the company list.

Before beginning our review, we will set out certain general standards that have guided us in our selection. We have approached the allocation factor on the basis that it should reflect the realities of the FIFRA data compensation scheme and the objectives that Congress intended to achieve when it included those provisions in the statute. We have concluded that Congress did not establish the process

for data compensation so that each individual follow-on registration would bear a proportionate share of the compensable data costs incurred by the pioneer registrant. Rather, the statute first calls for a negotiated resolution where possible, with arbitration available where there is no such resolution. That process contemplates that the pioneer registrant will pursue a claim for data compensation against follow-on registrants that rely on its data. This structure clearly implies a discussion on overall company obligations for data use, not obligations on a registration by registration basis.

The underlying objective is to encourage competition at the manufacturing and sales level for the product involved by allowing data usage by new sellers of a product after its pioneer registrant has had a protected period in the market on the basis of its data submissions relied on to secure initial EPA approval. In this context, it makes sense to use the companies that use the registration process as the markers for allocation of the overall compensable cost bundle of the pioneer, rather than counting the overall number of EPA registrations for that purpose. The companies will deal with the compensation obligation as an overall issue, not registration by registration. Indeed, the record here clearly indicates that when the final compensation arrangement is put in place, it covers a general right for the follow-on applicant to rely on the pioneer's data filed at EPA (although rights to use future data supplied by the pioneer may not be covered).

We learn from the record that EPA issues registrations for the basic chemical product that is used for purposes covered by the statute, as well as for individual end use formulations that contain that basic chemical. In the allocation process, we have concluded that it is the holders of the registrations for the technical chemical product that should be included in the *per capita* head count. It is those entities that manufacture and sell the basic product. The Congressional objective of fostering competition would have the most impact and meaning at that level of the market. Entities that obtain registrations for end use formulations they will offer for sale are dependent on the effectiveness of competition at the manufacturing level. We are unwilling to dilute the individual data compensation

liability of manufacturing registrants by counting large numbers of formulators who register only in order to sell end use products that contain that basic chemical. EPA itself has noted this central role of the registrants of the technical chemical product. In a passage from 1978 U.S. Code Cong. & Ad. News at 1976 quoted in PBI-Gordon Corp. v. Thomas, 609 F. Supp. 135, 141 n.6 (W.D. Mo. 1985) (emphasis added), the EPA Administrator stated that "it is the technical material which becomes the focal point for registration, rather than the end-use registrations.... This would mean that the issues of compensation for the most expensive data ... would be worked out *among the registrants of technical products*...."

The record provides us with some history of Monsanto's specific dealings in the data compensation arena for glyphosate. In reviewing the list of registrants, we have concluded that we should take that history into account. Specifically, we conclude that any registrant that has reached a bargained-for data compensation outcome with Monsanto should be included in the head count.

Finally, we have concluded that the allocation implications of indirect contributions to covering data compensation costs, such as inclusion of that cost responsibility in the purchase price of Monsanto products, should be considered only on a case by case basis for such companies.

With these general guidelines in mind, we have addressed Monsanto's proposals for excluding registrants from the *per capita* head count. The first category presented by Monsanto is state and local needs registrations. We did not eliminate any companies simply on the basis of their inclusion in this screen.

The second screen is cancelled registrations. This list covers 38 company names, 36 of which involve cancellations of registrations of end-use formulations. and involve cancellation of technical chemical registrations and those companies are addressed below.) We will eliminate 32 company names based on their inclusion in this screen. Award Appendix A, Key 2. The listed companies from this screen that we did not eliminate are:

They will be discussed elsewhere. The 32 eliminated companies held

registrations for end use formulations which have now been cancelled. In these circumstances, we do not regard them as realistic current participants in the data compensation arena. Nor do we believe that they would have been included if their registrations for end use formulations were still active. As we discuss below, it is our broader conclusion that the *per capita* count should be based on holders of technical chemical registrations.

The next screen is transferred registrations. Describing our treatment of these in the head count is somewhat complex. There is a total of 26 company names listed as transferors of registrations. Six of these listed transferor companies will not be considered for exclusion based on this screen because they are conceded by Monsanto as includible in the head count. Award Appendix A, Key 3. An additional ten of the listed transferor companies transferred the registration to a company that will be included in the head count. Award Appendix A, Key 4. We will not include these ten transferor companies in the head count because we conclude that, in the arena of data compensation, it is not realistic to assume that, at the time Monsanto pursues its compensation rights, it could or would obtain compensation from both the company holding the registration and its former holder. Three of the companies listed as transferors have already been excluded from the head count based on the cancellation screen. There is nothing about the transferred registrations listed here that merits restoring them to the head count. Award Appendix A, Key 5. One listed transferor company will be excluded from the head count because the transferred registration was shown in the record to be in the formulator's exemption category. Award Appendix A, Key 6. For reasons discussed below, we are not including such companies in the count on the basis of such registrations. That leaves six companies listed in the transfer screen to be considered. Award Appendix A, Key 7. Five of them transferred end use registrations. As previously noted, we have concluded that the head count should be based on holders of technical chemical registrations and we will not count these companies on the basis that they transferred end use registrations. There is one transferor of a technical chemical registration. Award

Appendix A, Key 8. However, that registration was transferred to a company that will be included in the head count. Award Appendix A, Key 9. In these circumstances, the transferor company, no longer the holder of any registrations, is not a realistic target in the data compensation arena and will not be counted. In summary, then, our review of the 26 names in the transfer screen results in a subtraction of an additional 16 names from the initial count of 114.

The next screen is a list of companies with active registrations for end-use formulations. A number of these companies will be retained in the head count for reasons unrelated to their presence on this list. However, 28 companies listed here will be removed from the head count on the basis of our conclusion, discussed above, that the allocation of compensable costs should be based on holders of registrations for the technical chemical product. Award Appendix A, Key 10.

Nine of the remaining names are shown by the record to be subject to the formulator's exemption. Award Appendix A, Key 11. We will not include eight of these companies in the head count.

FIFRA § 3(c)(2)(D) states:

No applicant for registration of a pesticide who proposes to purchase a registered pesticide from another producer in order to formulate such purchased pesticide into the pesticide that is the subject of the application shall be required to --

- (i) submit or cite data pertaining to such purchased product; or
- (ii) offer to pay reasonable compensation otherwise required by paragraph (1)(D) of this subsection for the use of any such data.

We recognize that, when establishing this treatment of registrants who purchase a registered pesticide from a registered manufacturer for use in a formulation, Congress was aware that the price of the product would include some component covering the data generation costs. However, as discussed above, we have concluded that we should consider the realities of the compensation scheme established in FIFRA Section 3(c)(1)(F) and the competitive objectives that Congress intended to achieve with that scheme. One of those realities is that, despite that data-related component in the

formulator's product price, Monsanto, and other similarly situated data submitters, cannot make a data compensation claim against a formulator and bring that formulator into the arena where it seeks the cost recovery provided for in FIFRA Section 3(c)(1)(F). In those circumstances, it is inappropriate to dilute the cost responsibility of those entities from which the data submitter can seek recovery.

Moreover, as noted in Monsanto's Brief at fn. 67, the dilution that results from including formulator exempt entities can lead to anomalous mathematical results. For example, for a market in which there are two large producers and one small formulator, without the formulator, the allocation is 50/50; with the formulator, the allocation is one-third each. The data submitter can only recover one-third from the other producer, but has little prospect of data cost recovery from sales to the small formulator.

Finally, we note that, where there are multiple registrants that manufacture the technical product, the pioneer data submitter has no assurance that the formulator will buy the product from it, rather than from other manufacturing registrants.

For all of these reasons, we will not include the eight formulator exempt registrants in the head count.

We will not address 24 of the companies individually, but include them in the head count because they are conceded by Monsanto to merit that treatment in allocation. Award Appendix A, Key 12. We will add six companies to the head count because it is shown in the record that they entered into data compensation settlements with Monsanto. Award Appendix A, Key 13. Without regard to the present status of any registrations they may have held, they actively participated in the data compensation scheme established in FIFRA Section 3(c)(1)(F). On this basis alone, they must be recognized in the allocation factor. Monsanto cannot strike a compensation bargain with a registrant and then ignore it in establishing the amount of compensation it is entitled to from others.

We will address seven more companies individually. We will include [redacted] in the head count. They hold technical registrations but Monsanto proposes excluding them from the count because they presently purchase their supply of glyphosate from a registered manufacturer in the count. We find that Monsanto has not satisfied its burden of proof for their exclusion. The present supply arrangement could end or other circumstances could arise that might realistically cause Monsanto to assert data compensation rights against them based on their technical registrations. We do not find that Monsanto has met its burden of proof for the exclusion of [redacted]. It asserts that [redacted] and [redacted] are the "same". However, we do not have any definitive evidence of the present relationship between them and cannot exclude [redacted] as a data compensation target. We will exclude [redacted] which is a subsidiary of [redacted] a company in the head count. We do not regard [redacted] as a realistic independent target for a data compensation claim in those circumstances. We will exclude [redacted] from the head count. It has a registration transferred to it by [redacted] which is in the head count. In these circumstances, we find that treating [redacted] an independent target for compensation is sufficiently unlikely to warrant exclusion.

We will include [redacted] in the head count. It has an end-use registration, and by that standard would not be counted. However, it obtained that registration from a transfer to it by Monsanto. Since Monsanto and [redacted] have dealt directly with each other in this way, it seems appropriate for [redacted] to be counted.

Thus, this review of individual companies has added four more to the head count. Award Appendix A, Key 14.

Next, in its discussion of allocation issues, Ritter addresses certain provisions of two settlement agreements that Monsanto has entered into concerning data compensation. Ritter Brief at 74-76. In one of them, the parties addressed the possibility of future submissions of additional or replacement data to support certain categories of glyphosate registrations. They agreed that in certain

circumstances, carefully defined in the contract, each party would pay _____ of the data generation costs and have _____ ownership of the data thus cost-shared. Elaborate arrangements were set forth for the mechanics of such cost sharing. Citing these contractual arrangements, Ritter argues that, for all Monsanto data generation costs incurred after the contractually operative date, Ritter's responsibility for the costs involved must be discounted by _____. Id. at 75-76.

Monsanto provided testimony by _____ a long time Monsanto employee with direct responsibility for dealings with certain Monsanto customers, including the company that entered into this settlement agreement. _____ testified that he had no recollection of any instance in which this data cost sharing arrangement was implemented, buttressing that recollection with the observation that Monsanto does not like shared data, preferring to develop its own.

In a separate sub-section of the referenced settlement agreement, the parties actually addressed the FIFRA data compensation issue Ritter seeks to raise here. They provided that Monsanto would be responsible for handling matters under FIFRA Section 3(C)(1)(F), keeping the other party informed and dividing any covered compensation equally between them.

There is nothing in the provisions of this settlement which would permit Ritter simply to avoid paying _____ of any portion of the compensation owed by them. There is no basis in the record for concluding that the settlement's potential joint ownership arrangement ever became operative for any data. Even if it had, there would be no basis for excusing Ritter's payment obligation. It would simply obligate Monsanto to share the relevant portion of the proceeds it received with another entity.

In another settlement agreement between Monsanto and another company, there are provisions covering data submissions after the date of the agreement. They call for a _____ cost sharing and ownership for such future data submissions. Again, explicit arrangements for payment of the _____ share to Monsanto are included. _____ testified that he also had dealings with

this company in his responsibilities for Monsanto. He had no recollection of data sharing payments to Monsanto under these provisions. We conclude that there is no evidence to support a conclusion that the necessary steps have been taken to create an ownership share by the other party to this agreement.

We note, in this connection, a Monsanto data response, placed in the record here, states that there are no entities other than Monsanto that have a non-statutory right or permission to own data for which compensation is sought. Ritter's principal witness, [REDACTED] when offered the opportunity to challenge that response on the basis of her personal knowledge, did not do so. We conclude that there is nothing in this agreement to justify any discount to the amount of compensation for which Ritter is otherwise liable.

We will not make any adjustment to the amount of the Award on the basis of the two settlement agreements referenced by Ritter.

Accordingly, for the above reasons, the allocation factor we will apply to determine Ritter's share of the total compensable amount we have determined above will be 35 and we will not make any adjustments based on data ownership.

IV. CONFIDENTIALITY

As this Final Arbitration Award (the "Final Award") is dispositive of all issues in this arbitration proceeding, the Parties shall insure that Paragraph 21 of the Panel's Protective Order, dated October 28, 2011, is fully observed with respect to this Final Award. In this regard, they shall, among other things, notify the Panel within twenty (20) days of the date of this Final Award of their agreement that the Final Award may be released in its entirety, or that the Final Award may be publicly released with specific redactions, or that specified disputes concerning redactions require resolution by the Panel. In resolving any disputes, the Panel will take into consideration the public interest in providing a coherent public version of the Final Award. In the interim, no part of this Final Award will be publicly released.

V. AWARD OF THE ARBITRATORS

Based on the analysis above, and having considered all of the evidence and arguments in the record of this arbitration, we, the undersigned Arbitrators, having been designated in accordance with FIFRA, and having been duly sworn, and having duly heard the proofs and allegations of the Parties, do hereby, AWARD, as follows:

For Base Data Costs:

Technical and End-Use Data (SOC Exhibit 2)	\$ 17,753,684.00 ¹⁴
Roundup Ready Registration Related Data (SOC Exhibit 3)	12,451,000.00
Label Development Data Including Weed Resistance (SOC Exhibit 4)	15,095,482.00
Regulatory Management Costs	3,550,737.00 ¹⁵
EPA Tolerance Fees	147,375.00
Total for Base Data Costs	48,998,278.00
Inflation Adjustment Based on ECI	14,745,097.00 ¹⁶
Ritter's Per Capita Share of Total Amount for Data Costs and Inflation Adjustment	1/35 ¹⁷
Ritter's Per Capita Share of Inflation Adjustment	421,289.00
Ritter's Per Capita Share of Base Data Costs	1,399,950.00
AWARD AMOUNT:	1,821,239.00

In accordance with FIFRA Arbitration Rules 38 and 40 and by Order of the Panel, the administrative fees of the American Arbitration Association shall be borne as incurred. The fees and expenses of the Arbitrators shall be borne equally by the Parties.

¹⁴ After deleting Study Nos. 48-59, 61, 63 (already "0" since no claimed cost), 96 and 97.

¹⁵ 20% of allowed SOC Exh. No. 2 studies.

¹⁶ Adjusted after eliminating ECI amounts for deleted SOC Exh. No. 2 Studies. See Monsanto Rebuttal Exhibits 5 and 5A.

¹⁷ Based on 1/35th allocable share.

In accordance with FIFRA Arbitration Rules 38 and 40 and by Order of the Panel, the fees of the American Arbitration Association, totaling Thirteen Thousand Eight Hundred Fifty Dollars and Zero Cents (\$13,850.00) and the fees of the Arbitrators, totaling Five Hundred Sixty Six Thousand and Thirty Four Dollars and Fifty Nine Cents (\$566,034.59), shall be borne as incurred.

In accordance with FIFRA Arbitration Rule 40, the costs of the court reporters and transcripts of this proceeding, unless the Parties have otherwise agreed within ten (10) days from the date of this Final Arbitration Award, shall be shared equally by the Parties and shall be paid directly to the reporting agency.

The above amounts payable to Monsanto by Ritter shall be paid within thirty (30) days from the date of this Final Award, with no further interest, unless Ritter delays its payment, in whole or part, beyond such period of thirty (30) days, in which case the unpaid portion of this Final Award shall bear simple interest at the prime rate of interest plus 2%.

Except as may otherwise be provided herein or as may otherwise be agreed between the Parties, each Party shall pay its representative attorneys' fees, witness fees and related expenses in connection with this Arbitration.

This Final Award is in full settlement of all claims submitted to this Arbitration.

This Final Award may be executed in any number of counterparts, each of which shall be deemed an original, and all of which shall constitute together one and the same instrument.

June 20, 2013

Date

June 20, 2013

Date

June 20, 2013

Date

Howard G. Slavitt

Howard G. Slavitt, Chairman

George A. Avery

George A. Avery, Arbitrator

James W. Constable

James W. Constable, Arbitrator

APPENDIX A

{00287409v. (03343.00199)}

APPENDIX A
ALLOCATION FACTOR DETERMINATION

KEY

- | | | |
|--------------------------------------|--|---|
| 1 Duplicate Names | 6 Transferor in Formulators Exemption | 11 Formulator Exempt Companies Excluded |
| 2 Cancellation-based Eliminations | 7 Transferors Considered for Exclusion from Count | 12 Companies Included in Monsanto Count |
| 3 Transferors in Monsanto Count | 8 End-use Transferors | 13 Companies Added to Count Based on Settlements |
| 4 Transferee Companies in Head Count | 9 Transferor to Company in Head Count | 14 Companies Included in Count Through Individual Consideration |
| 5 Transfer/Cancellation Overlaps | 10 Companies Removed from Count on Basis of End-use Registration | |

COMPANIES IN HEAD COUNT ARE HIGHLIGHTED

10	
3, 12	
12	
2	
11, 13	
12	
10	
2	
2, 5	
12	
12	
1	
2	
3, 12	
10	

COMPANIES IN HEAD COUNT ARE HIGHLIGHTED

11	
1	
10	
10	
1	
12	
14	
2	
10	
10	
2	
4	
4, 13	
12	
1	
10	
14	
2	
14	
10	
7, 8	
2, 4	
2	
10	
12	
11, 14	
10	
7, 8	
14	

COMPANIES IN HEAD COUNT ARE HIGHLIGHTED

10	
10	
7, 8	
12	
14	
11	
4, 12	
1	
2, 5	
10	
2	
2, 5	
10	
12	
2	
2	
5	
2	
4	
10, 11	
12	
11	
2	
7, 8	
2	
1	
10	
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13	
10	

COMPANIES IN HEAD COUNT ARE HIGHLIGHTED

3, 12	
1	
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7, 13	
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11	
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10	
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7, 8	
13	
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12	
12	
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2	
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12	
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10	
1	

COMPANIES IN HEAD COUNT ARE HIGHLIGHTED

12	
12	
10	
13	
6	
4	
2, 4	
3, 12	
2	
12	
4	
10	
10	
2	
10	
2, 5	
2, 5	
2	
11	
11	
11	
2	